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# UNITED STATES DISTRICT COURT DISTRICT OF NEW JERSEY

MASIMO CORPORATION, a Delaware corporation,

Plaintiff,

V.

MINDRAY DS USA, INC., MINDRAY USA BIOMEDICAL ELECTRONICS CO., LTD., and MINDRAY MEDICAL INTERNATIONAL LTD., jointly and severally,

Defendants.

MINDRAY DS USA, INC., a Delaware corporation,

Counter-Plaintiff

V.

MASIMO CORPORATION, a Delaware corporation,

Counter-Defendant

Civil Action No. 14-405 (SDW)(MCA)

ANSWER AND COUNTERCLAIMS OF MINDRAY DS USA, INC. TO COMPLAINT

**DEMAND FOR JURY TRIAL** 

Mindray DS USA, Inc. ("Mindray USA"), by and through its undersigned attorneys, hereby answers and asserts counterclaims in response to the Complaint filed by Masimo Corporation ("Masimo"), as follows:

#### INTRODUCTION

1. Mindray USA admits that it is a party to a 1997 Restated Purchasing and Licensing Agreement ("the DS Agreement"). Mindray USA denies each and every remaining allegation of Paragraph 1 of Masimo's Complaint.

#### **IDENTIFICATION OF THE PARTIES**

- 2. Mindray USA admits that Masimo is a medical technology company. Mindray USA is without knowledge or information sufficient to form a belief regarding the remaining allegations of Paragraph 2 of Masimo's Complaint, and on that basis denies those allegations.
  - 3. Mindray USA admits the allegations of Paragraph 3 of Masimo's Complaint.
- 4. Mindray USA admits that Shenzhen Mindray Bio-Medical Electronics Co., Ltd. (Shenzhen Mindray) is a corporation organized and existing under the laws of the People's Republic of China and that has a place of business at Mindray Building, Keji 12th Road South, High-Tech Industrial Park, Nanshan, Shenzhen, People's of Republic of China. Mindray USA is without knowledge or information sufficient to form a belief regarding the remaining allegations of Paragraph 4 of Masimo's Complaint, and on that basis denies those allegations.
- 5. Mindray USA admits that Mindray Medical International Limited (MMIL) is a Cayman Islands corporation, and indirectly is a parent corporation of Mindray USA. Mindray USA denies that MMIL or Shenzhen Mindray directs or controls the activities of Mindray USA. Mindray USA is without knowledge or information sufficient to form a belief regarding the remaining allegations of Paragraph 5 of Masimo's Complaint, and on that basis denies those allegations.

#### **JURISDICTION AND VENUE**

6. Mindray USA admits that jurisdiction and venue are proper in New Jersey as to Mindray USA. Mindray USA denies that the express terms of the Licensing Agreement state "if

an action is brought by Masimo against [Mindray's predecessor-in-interest, Datascope Corp.] under this Agreement shall be brought in New Jersey." Mindray USA further denies that MMIL or Shenzhen Mindray are subject to the jurisdiction of the New Jersey courts. Mindray USA is without knowledge or information sufficient to form a belief regarding the remaining allegations of Paragraph 6 of Masimo's Complaint, and on that basis denies those allegations.

7. Mindray USA admits that it is a resident of Bergen County, and that venue is proper in New Jersey. Mindray USA denies the remaining allegations of Paragraph 7 of Masimo's Complaint.

## FACTS COMMON TO ALL COUNTS

- 8. Mindray USA admits that Masimo is a medical technology company. Mindray USA is without knowledge or information sufficient to form a belief regarding the remaining allegations of Paragraph 8 of Masimo's Complaint, and on that basis denies those allegations...
- 9. Mindray USA admits that Masimo SET® ("Masimo SET") is pulse oximetry technology that allows physicians to monitor the oxygen saturation of a patient's blood. Mindray USA denies the remaining allegations of Paragraph 9 of Masimo's Complaint.
- 10. Mindray USA admits that there may be times when it is critical to monitor a patient's blood oxygenation. Mindray USA is without knowledge or information sufficient to form a belief regarding the remaining allegations of Paragraph 10 of Masimo's Complaint, and on that basis, denies those allegations.
- 11. Mindray USA admits that Masimo licenses Masimo SET circuit boards for integration into patient monitoring products throughout the world. Mindray USA is without knowledge or information sufficient to form a belief regarding the remaining allegations of Paragraph 11 of Masimo's Complaint, and on that basis, denies those allegations.
- 12. Responding for itself only, Mindray USA admits that it imports, markets, sells, and distributes medical devices in the United States that include noninvasive patient monitoring technologies, such as those manufactured by Masimo. Mindray USA does not, and need not,

respond to the allegations of Paragraph 12 of Masimo's Complaint insofar as those allegations are directed to Shenzhen Mindray or MMIL.

- 13. Responding for itself only, Mindray USA states that the allegations of Paragraph 13 of Masimo's Complaint are unintelligible. Accordingly, Mindray USA is without knowledge or information sufficient to form a belief regarding the allegations of Paragraph 13 of Masimo's Complaint, and on that basis, denies those allegations. Mindray USA does not, and need not, respond to the allegations of Paragraph 13 of Masimo's Complaint insofar as those allegations are directed to Shenzhen Mindray or MMIL.
- 14. Responding for itself only, Mindray USA admits that some Mindray USA products utilize Masimo's pulse oximetry technology while others rely on competing pulse oximetry technology; the remaining allegations of Paragraph 14 of Masimo's Complaint calls for a legal conclusion to which no response is required by Mindray USA. Mindray USA does not, and need not, respond to the allegations of Paragraph 14 of Masimo's Complaint insofar as those allegations are directed to Shenzhen Mindray or MMIL.
- 15. Responding only for itself, Mindray USA denies the allegations of Paragraph 15 of Masimo's Complaint and each and every subpart thereof. Mindray USA does not, and need not, respond to the allegations of Paragraph 15 of Masimo's Complaint insofar as those allegations are directed to Shenzhen Mindray or MMIL.
- 16. Responding for itself only, Mindray USA states that the allegations of Paragraph 16 of Masimo's Complaint are unintelligible in that they allege that "Mindray" (which is defined as including Mindray USA) "has not treated ... Mindray USA independently..." Further responding only for itself, to the extent that the allegations of Paragraph 16 of Masimo's Complaint can be understood, Mindray USA denies that it is an alter ego of either or both Shenzhen Mindray and MMIL. The remaining allegations of Paragraph 16 of Masimo's Complaint call for legal conclusions to which no response is required by Mindray USA. Mindray USA does not, and need not, respond to the allegations of Paragraph 16 of Masimo's Complaint insofar as those allegations are directed to Shenzhen Mindray or MMIL.

- 17. Responding for itself only, Mindray USA denies the allegations of Paragraph 17 of Masimo's Complaint and each and every subpart thereof. Mindray USA does not, and need not, respond to the allegations of Paragraph 17 of Masimo's Complaint insofar as those allegations are directed to Shenzhen Mindray or MMIL.
- 18. Responding for itself only, Mindray USA is without knowledge or information sufficient to form a belief regarding whether MMIL completed its acquisition of Datascope's monitoring device business on May 15, 2008, and on that basis, denies those allegations. The remaining allegations of Paragraph 18 of Masimo's Complaint call for a legal conclusion to which no response is required by Mindray USA. Mindray USA does not, and need not, respond to the allegations of Paragraph 18 of Masimo's Complaint insofar as those allegations are directed to Shenzhen Mindray or MMIL.
- 19. Responding for itself only, Mindray USA admits that the DS Agreement was amended, but denies that it was amended on several occasions. The remaining allegations of Paragraph 19 of Masimo's Complaint call for legal conclusions to which no response is required by Mindray USA. Mindray USA does not, and need not, respond to the allegations of Paragraph 19 of Masimo's Complaint insofar as those allegations are directed to Shenzhen Mindray or MMIL.
- 20. Responding for itself only, Mindray USA denies the allegations of Paragraph 20 of Masimo's Complaint. Mindray USA does not, and need not, respond to the allegations of Paragraph 20 of Masimo's Complaint insofar as those allegations are directed to Shenzhen Mindray or MMIL.
- 21. Responding for itself only, Mindray USA denies the allegations of Paragraph 21 of Masimo's Complaint and each and every subpart thereof. Mindray USA does not, and need not, respond to the allegations of Paragraph 21 of Masimo's Complaint insofar as those allegations are directed to Shenzhen Mindray or MMIL.
- 22. Responding for itself only, Mindray USA denies the allegations of Paragraph 22 of Masimo's Complaint. Mindray USA does not, and need not, respond to the allegations of

Paragraph 22 of Masimo's Complaint insofar as those allegations are directed to Shenzhen Mindray or MMIL.

- 23. Responding for itself only, Mindray USA denies the allegations of Paragraph 23 of Masimo's Complaint. Mindray USA does not, and need not, respond to the allegations of Paragraph 23 of Masimo's Complaint insofar as those allegations are directed to Shenzhen Mindray or MMIL.
- 24. Responding for itself only, Mindray USA denies the allegations of Paragraph 24 of Masimo's Complaint. Mindray USA does not, and need not, respond to the allegations of Paragraph 24 of Masimo's Complaint insofar as those allegations are directed to Shenzhen Mindray or MMIL.
- 25. Responding for itself only, Mindray USA denies the allegations of Paragraph 25 of Masimo's Complaint and each and every subpart thereof. Mindray USA does not, and need not, respond to the allegations of Paragraph 25 of Masimo's Complaint insofar as those allegations are directed to Shenzhen Mindray or MMIL.

## **FIRST COUNT**

## (Breach of Contract)

- 26. Mindray USA incorporates by reference its responses to the preceding paragraphs of Masimo's Complaint.
- 27. Responding for itself only, Mindray USA denies the allegations of Paragraph 27 of Masimo's Complaint. Mindray USA does not, and need not, respond to the allegations of Paragraph 27 of Masimo's Complaint insofar as those allegations are directed to Shenzhen Mindray or MMIL.
- 28. Responding for itself only, Mindray USA denies the allegations of Paragraph 28 of Masimo's Complaint each and every subpart thereof. Mindray USA does not, and need not, respond to the allegations of Paragraph 28 of Masimo's Complaint insofar as those allegations are directed to Shenzhen Mindray or MMIL.
  - 29. Responding for itself only, Mindray USA denies the allegations of Paragraph 29

of Masimo's Complaint. Mindray USA does not, and need not, respond to the allegations of Paragraph 29 of Masimo's Complaint insofar as those allegations are directed to Shenzhen Mindray or MMIL.

- 30. Responding for itself only, Mindray USA denies the allegations of Paragraph 30 of Masimo's Complaint. Mindray USA does not, and need not, respond to the allegations of Paragraph 30 of Masimo's Complaint insofar as those allegations are directed to Shenzhen Mindray or MMIL.
- 31. Responding for itself only, Mindray USA denies the allegations of Paragraph 31 of Masimo's Complaint. Mindray USA does not, and need not, respond to the allegations of Paragraph 31 of Masimo's Complaint insofar as those allegations are directed to Shenzhen Mindray or MMIL.
- 32. Responding for itself only, Mindray USA denies the allegations of Paragraph 32 of Masimo's Complaint. Mindray USA does not, and need not, respond to the allegations of Paragraph 32 of Masimo's Complaint insofar as those allegations are directed to Shenzhen Mindray or MMIL.
- 33. Responding for itself only, Mindray USA responds that the allegations of Paragraph 33 of Masimo's Complaint call for legal conclusions to which no response is required by Mindray USA. Mindray USA does not, and need not, respond to the allegations of Paragraph 33 of Masimo's Complaint insofar as those allegations are directed to Shenzhen Mindray or MMIL.
- 34. Responding for itself only, Mindray USA denies the allegations of Paragraph 34 of Masimo's Complaint. Mindray USA does not, and need not, respond to the allegations of Paragraph 34 of Masimo's Complaint insofar as those allegations are directed to Shenzhen Mindray or MMIL.
- 35. Responding for itself only, Mindray USA denies the allegations of Paragraph 35 of Masimo's Complaint. Mindray USA does not, and need not, respond to the allegations of

Paragraph 35 of Masimo's Complaint insofar as those allegations are directed to Shenzhen Mindray or MMIL.

36. Responding for itself only, Mindray USA denies the allegations of Paragraph 36 of Masimo's Complaint. Mindray USA does not, and need not, respond to the allegations of Paragraph 36 of Masimo's Complaint insofar as those allegations are directed to Shenzhen Mindray or MMIL.

## RELIEF REQUESTED FOR FIRST COUNT

Responding for itself only, Mindray USA denies that Masimo is entitled to judgment against Mindray USA as follows:

- A. Awarding Masimo compensatory damages because Masimo has suffered no compensatory damages;
- B. Awarding Masimo incidental and consequential damages because Masimo has suffered no incidental and consequential damages;
- C. Awarding Masimo pre- and post-judgment interest at the maximum legal rate because Masimo is not entitled to pre- and post-judgment interest at the maximum legal rate;
- D. Awarding Masimo costs of suit and reasonable attorneys' fees because Masimo is not entitled to costs of suit and reasonable attorneys' fees;
- E. Directing Mindray to provide Masimo with an accounting of all gains, profits, and advantages derived by Mindray from its contract breaches and wrongful conduct towards

  Masimo because Masimo is not entitled to an accounting, Mindray USA has not breached a contract with Masimo and has not engaged in wrongful conduct towards Masimo, and to

  Mindray USA's knowledge, neither MMIL nor Shenzhen Mindray have breached a contract with Masimo nor have either engaged in wrongful conduct towards Masimo;
- F. Preliminarily and permanently enjoining Mindray, its officers, agents, servants, employees and attorneys, and those persons in active concert or participation with them from engaging in any act or practice that constitutes a breach of the Licensing Agreement, because Masimo is not entitled to injunctive relief given that, among other things: (1) Masimo has not suffered nor will it suffer irreparable harm because of Mindray USA's conduct; (2) any harm to Masimo would be outweighed by the harm to Mindray USA; (3) Masimo has an adequate remedy at law even if it were to prevail in this action; and (4) the public interest would not be served by an injunction in favor of Masimo; and
- G. Awarding Masimo such other and further relief as the Court deems just and equitable because Masimo is not entitled to other and further relief, and other and further relief

would be unjust and inequitable.

Mindray USA does not, and need not, respond to the allegations of Masimo's request for relief for its First Count insofar as those allegations are directed to Shenzhen Mindray or MMIL.

## **SECOND COUNT**

## (Breach of the Implied Covenant of Good Faith and Fair Dealing)

- 37. Mindray USA incorporates by reference its responses to the preceding paragraphs of Masimo's Complaint.
- 38. Responding for itself only, Mindray USA responds that the allegations of Paragraph 38 of Masimo's Complaint call for a legal conclusion to which no response is required by Mindray USA. Mindray USA does not, and need not, respond to the allegations of Paragraph 38 of Masimo's Complaint insofar as those allegations are directed to Shenzhen Mindray or MMIL.
- 39. Responding for itself only, Mindray USA responds that the allegations of Paragraph 39 of Masimo's Complaint call for a legal conclusion to which no response is required by Mindray USA. Mindray USA does not, and need not, respond to the allegations of Paragraph 39 of Masimo's Complaint insofar as those allegations are directed to Shenzhen Mindray or MMIL.
- 40. Responding for itself only, Mindray USA responds that the allegations of Paragraph 40 of Masimo's Complaint call for a legal conclusion to which no response is required by Mindray USA. Mindray USA does not, and need not, respond to the allegations of Paragraph 40 of Masimo's Complaint insofar as those allegations are directed to Shenzhen Mindray or MMIL.
- 41. Responding for itself only, Mindray USA denies the allegations of Paragraph 41 of Masimo's Complaint. Mindray USA does not, and need not, respond to the allegations of Paragraph 41 of Masimo's Complaint insofar as those allegations are directed to Shenzhen Mindray or MMIL.

- 42. Responding for itself only, Mindray USA denies the allegations of Paragraph 42 of Masimo's Complaint. Mindray USA does not, and need not, respond to the allegations of Paragraph 42 of Masimo's Complaint insofar as those allegations are directed to Shenzhen Mindray or MMIL.
- 43. Responding for itself only, Mindray USA denies the allegations of Paragraph 43 of Masimo's Complaint. Mindray USA does not, and need not, respond to the allegations of Paragraph 43 of Masimo's Complaint insofar as those allegations are directed to Shenzhen Mindray or MMIL.

## RELIEF REQUESTED FOR SECOND COUNT

Responding for itself only, Mindray USA denies that Masimo is entitled to judgment against Mindray USA as follows:

- A. Awarding Masimo compensatory damages;
- B. Awarding Masimo incidental and consequential damages;
- C. Awarding Masimo pre- and post-judgment interest at the maximum legal rate;
- D. Awarding Masimo costs of suit and reasonable attorneys' fees;
- E. Directing Mindray to provide Masimo with an accounting of all gains, profits, and advantages derived by Mindray from its contract breaches and wrongful conduct towards Masimo;
- F. Preliminarily and permanently enjoining Mindray, its officers, agents, servants, employees and attorneys, and those persons in active concert or participation with them from engaging in any act or practice that constitutes a breach of the Licensing Agreement or the implied covenant of good faith and fair dealing contained therein, because Masimo is not entitled to injunctive relief given that, among other things: (1) Masimo has not suffered nor will it suffer irreparable harm because of Mindray USA's conduct; (2) any harm to Masimo would be outweighed by the harm to Mindray USA; (3) Masimo has an adequate remedy at law even if it were to prevail in this action; and (4) the public interest would not be served by an injunction in favor of Masimo; and

G. Awarding Masimo such other and further relief as the Court deems just and equitable because Masimo is not entitled to other and further relief, and other and further relief would be unjust and inequitable.

Mindray USA does not, and need not, respond to the allegations of Masimo's request for relief for its Second Count insofar as those allegations are directed to Shenzhen Mindray or MMIL.

## THIRD COUNT

# (Declaratory Relief)

- 44. Mindray USA incorporates by reference its responses to the preceding paragraphs of Masimo's Complaint.
- 45. Responding for itself only, Mindray USA responds that the allegations of Paragraph 45 of Masimo's Complaint call for a legal conclusion to which no response is required by Mindray USA. Mindray USA does not, and need not, respond to the allegations of Paragraph 45 of Masimo's Complaint insofar as those allegations are directed to Shenzhen Mindray or MMIL.
- 46. Responding for itself only, Mindray USA denies the allegations of Paragraph 46 of Masimo's Complaint, and further responds that to the extent the allegations of Paragraph 46 of Masimo's Complaint call for a legal conclusion, no response is required by Mindray USA. Mindray USA does not, and need not, respond to the allegations of Paragraph 46 of Masimo's Complaint insofar as those allegations are directed to Shenzhen Mindray or MMIL.
- 47. Responding for itself only, Mindray USA admits that Masimo purports to seek "a judicial determination of the respective rights and duties of Masimo and Mindray under the Licensing Agreement" but denies that "Mindray" as defined in Masimo's Complaint, and as used in the allegations of Paragraph 47 of the Masimo's Complaint, is subject to any rights or duties under the DS Agreement. Further responding for itself only, Mindray USA responds that to the extent the allegations of Paragraph 47 of Masimo's Complaint call for a legal conclusion, no response is required by Mindray USA. Mindray USA does not, and need not, respond to the

allegations of Paragraph 47 of Masimo's Complaint insofar as those allegations are directed to Shenzhen Mindray or MMIL.

- 48. Responding for itself only, Mindray USA admits that Masimo purports to seek "a declaration that Mindray International, Mindray Shenzhen and Mindray USA are parties to and in material breach of the Licensing Agreement" but denies that Shenzhen Mindray or MMIL are parties to the DS Agreement, or that there is any breach thereof as alleged in Paragraph 48 of the Masimo's Complaint. Further responding for itself only, Mindray USA responds that to the extent the allegations of Paragraph 48 of Masimo's Complaint call for a legal conclusion, no response is required by Mindray USA. Mindray USA does not, and need not, respond to the allegations of Paragraph 48 of Masimo's Complaint insofar as those allegations are directed to Shenzhen Mindray or MMIL.
- 49. Responding for itself only, Mindray USA responds that the allegations of Paragraph 49 of Masimo's Complaint call for a legal conclusion to which no response is required by Mindray USA. Mindray USA does not, and need not, respond to the allegations of Paragraph 49 of Masimo's Complaint insofar as those allegations are directed to Shenzhen Mindray or MMIL.

## RELIEF REQUESTED FOR THIRD COUNT

Responding for itself only, Mindray USA denies that Masimo is entitled to judgment against Mindray USA as follows:

- A. Declaring that Mindray International or Mindray Shenzhen are parties to the Licensing Agreement because MMIL and Shenzhen Mindray are not parties to the Licensing Agreement;
- B. Declaring that the terms of the Licensing Agreement, including those set forth in Sections 4.1, 4.6, and 5.1 are valid and binding upon Mindray International or Mindray Shenzhen because the terms of the Licensing Agreement, including those set forth in Sections 4.1, 4.6, and 5.1 are not valid and not binding upon MMIL Shenzhen Mindray;
- C. Awarding Masimo such other and further relief as the Court deems just and equitable because Masimo is not entitled to other and further relief, and other and further relief would be unjust and inequitable.

Mindray USA does not, and need not, respond to the allegations of Masimo's request for relief for its Third Count insofar as those allegations are directed to Shenzhen Mindray or MMIL.

## **FOURTH COUNT**

#### (Tortious Interference With Prospective Economic Advantage)

- 50. Mindray USA incorporates by reference its responses to the preceding paragraphs of Masimo's Complaint.
- 51. Mindray USA does not, and need not, respond to the allegations of Paragraph 51 of Masimo's Complaint insofar as those allegations are directed to Shenzhen Mindray or MMIL.
- 52. Responding for itself only, Mindray USA responds that the allegations of Paragraph 52 of Masimo's Complaint call for a legal conclusion to which no response is required by Mindray USA. Mindray USA does not, and need not, respond to the allegations of Paragraph 52 of Masimo's Complaint insofar as those allegations are directed to Shenzhen Mindray or MMIL.

- 53. Mindray USA does not, and need not, respond to the allegations of Paragraph 53 of Masimo's Complaint insofar as those allegations are directed to Shenzhen Mindray or MMIL.
- 54. Mindray USA does not, and need not, respond to the allegations of Paragraph 54 of Masimo's Complaint insofar as those allegations are directed to Shenzhen Mindray or MMIL.
- 55. Responding for itself only, Mindray USA denies the allegations of Paragraph 55 of Masimo's Complaint. Mindray USA does not, and need not, respond to the allegations of Paragraph 55 of Masimo's Complaint insofar as those allegations are directed to Shenzhen Mindray or MMIL.
- 56. Mindray USA does not, and need not, respond to the allegations of Paragraph 56 of Masimo's Complaint insofar as those allegations are directed to Shenzhen Mindray or MMIL.
- 57. Mindray USA does not, and need not, respond to the allegations of Paragraph 57 of Masimo's Complaint insofar as those allegations are directed to Shenzhen Mindray or MMIL.
- 58. Mindray USA does not, and need not, respond to the allegations of Paragraph 58 of Masimo's Complaint insofar as those allegations are directed to Shenzhen Mindray or MMIL.
- 59. Mindray USA does not, and need not, respond to the allegations of Paragraph 59 of Masimo's Complaint insofar as those allegations are directed to Shenzhen Mindray or MMIL.
- 60. Responding for itself only, Mindray USA denies the allegations of Paragraph 60 of Masimo's Complaint. Mindray USA does not, and need not, respond to the allegations of Paragraph 60 of Masimo's Complaint insofar as those allegations are directed to Shenzhen Mindray or MMIL.

## RELIEF REQUESTED FOR FOURTH COUNT

Mindray USA does not, and need not, respond to Masimo's request for relief for its Fourth Count insofar as that requested relief is directed to Shenzhen Mindray and MMIL.

## FIFTH COUNT

## (Tortious Interference With Contract)

61. Mindray USA incorporates by reference its responses to the preceding paragraphs of Masimo's Complaint.

- 62. Mindray USA does not, and need not, respond to the allegations of Paragraph 61 of Masimo's Complaint insofar as those allegations are directed to Shenzhen Mindray or MMIL.
- 63. Mindray USA does not, and need not, respond to the allegations of Paragraph 63 of Masimo's Complaint insofar as those allegations are directed to Shenzhen Mindray or MMIL.
- 64. Responding for itself only, Mindray USA responds that the allegations of Paragraph 64 of Masimo's Complaint call for a legal conclusion to which no response is required by Mindray USA. Mindray USA does not, and need not, respond to the allegations of Paragraph 64 of Masimo's Complaint insofar as those allegations are directed to Shenzhen Mindray or MMIL.
- 65. Responding for itself only, Mindray USA responds that the allegations of Paragraph 65 of Masimo's Complaint call for a legal conclusion to which no response is required by Mindray USA. Mindray USA does not, and need not, respond to the allegations of Paragraph 65 of Masimo's Complaint insofar as those allegations are directed to Shenzhen Mindray or MMIL.
- 66. Responding for itself only, Mindray USA denies the allegations of Paragraph 66 of Masimo's Complaint. Mindray USA does not, and need not, respond to the allegations of Paragraph 66 of Masimo's Complaint insofar as those allegations are directed to Shenzhen Mindray or MMIL.
- 67. Mindray USA does not, and need not, respond to the allegations of Paragraph 67 of Masimo's Complaint insofar as those allegations are directed to Shenzhen Mindray or MMIL.
- 68. Mindray USA does not, and need not, respond to the allegations of Paragraph 68 of Masimo's Complaint insofar as those allegations are directed to Shenzhen Mindray or MMIL.
- 69. Responding for itself only, Mindray USA denies the allegations of Paragraph 69 of Masimo's Complaint. Mindray USA does not, and need not, respond to the allegations of Paragraph 69 of Masimo's Complaint insofar as those allegations are directed to Shenzhen Mindray or MMIL.

## RELIEF REQUESTED FOR FIFTH COUNT

Mindray USA does not, and need not, respond to Masimo's request for relief for its Fifth Count insofar as that requested relief is directed to Shenzhen Mindray and MMIL.

## AFFIRMATIVE DEFENSES

Mindray USA asserts the following affirmative defenses without admitting or acknowledging that it bears the burden of proof as to any of them.

#### FIRST AFFIRMATIVE DEFENSE

#### (Failure to State a Claim)

1. Masimo's First through Fifth Claims each fail to state a claim upon which relief may be granted.

#### SECOND AFFIRMATIVE DEFENSE

## (Failure of Consideration)

2. Masimo's claims and requested relief based on the DS Agreement and amendments thereto are barred by failure of consideration.

#### THIRD AFFIRMATIVE DEFENSE

## (Failure To Perform)

3. Masimo's claims and requested relief based on the DS Agreement and amendments thereto are barred by Masimo's failure to perform in accordance with its duties and obligations under the DS Agreement and amendments thereto.

## FOURTH AFFIRMATIVE DEFENSE

## (Excuse of Performance)

4. Mindray USA has fully performed all obligations under the DS Agreement and amendments thereto except for any conditions excused by virtue of Masimo's anticipatory repudiation and/or Masimo's contractual breach.

#### FIFTH AFFIRMATIVE DEFENSE

(Illegality)

 Masimo's claims and requested relief based on the DS Agreement and amendments thereto are barred by the illegality created by the anti-competitive provisions of the DS Agreement and amendments thereto.

## SIXTH AFFIRMATIVE DEFENSE

## (Statutes of Limitation)

6. Masimo's claims for damages are limited in whole or in part by applicable statutes of limitation.

## SEVENTH AFFIRMATIVE DEFENSE

## (Contract of Adhesion)

7. Masimo's claims based on the DS Agreement and amendments thereto are barred in whole or in part in light of provisions that are the product of disparate bargaining power and/or the failure of knowing and voluntary agreement by Mindray USA.

## EIGHTH AFFIRMATIVE DEFENSE

## (No Immediate or Irreparable Injury)

8. Masimo is not entitled to injunctive relief at least because: (1) Masimo has not suffered nor will it suffer irreparable harm because of Mindray USA's conduct; (2) any harm to Masimo would be outweighed by the harm to Mindray USA; (3) Masimo has an adequate remedy at law even if it were to prevail in this action; and (4) the public interest would not be served by an injunction in favor of Masimo.

#### NINTH AFFIRMATIVE DEFENSE

#### (License)

9. Masimo has not been injured by any action undertaken by Mindray USA with respect to pulse oximetry technology incorporating Shenzhen Mindray SpO2 algorithms because such products are directly or impliedly licensed under the DS Agreement.

## TENTH AFFIRMATIVE DEFENSE

## (Failure to Mitigate)

10. Masimo's claims for damages are barred in whole or in part because, by the exercise of reasonable effort, Masimo could have mitigated the amount of damages it suffered, if any. Masimo has failed and refused, and continues to fail and refuse, to exercise a reasonable effort to mitigate its damages.

## OTHER AFFIRMATIVE DEFENSES

11. Mindray USA reserves the right to assert additional affirmative defenses during or upon completion of discovery.

#### JURY DEMAND

Mindray USA joins Masimo's request for a trial by jury of any and all issues in this action so triable.

# COUNTERCLAIMS

Mindray DS USA, Inc. ("Mindray USA") alleges the following counterclaims against Masimo Corporation ("Masimo"):

## **JURISDICTION AND VENUE**

- 1. Mindray USA asserts violations of federal antitrust law, specifically Sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1-2, and Section 3 of the Clayton Act, 15 U.S.C. § 14.
- 2. Mindray USA seeks monetary and equitable relief under Sections 4 and 16 of the Clayton Act, 15 U.S.C. §§ 15 & 26.
- 3. Mindray USA asserts counterclaims under the Federal Declaratory Judgment Act, 28 U.S.C. § 2, seeking declaratory judgments under the patent laws of the United States, United States Code Title 35, that the patents threatened to be asserted by Masimo are invalid, unenforceable, and not infringed.
- 4. Mindray USA asserts counterclaims of patent infringement under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*, and, in particular 35 U.S.C. § 271.
- 5. This Court has subject matter jurisdiction over these counterclaims pursuant to 28 U.S.C. §§ 1331, 1338(a), 1367(a), 2201, and 2202, and 35 U.S.C. § 1, *et seq*.
  - 6. Masimo has submitted to the personal jurisdiction of this Court.
- 7. Venue is proper in this district for the purpose of compulsory counterclaims pursuant to 28 U.S.C. § 1391, because this suit was filed in this District by Masimo. Venue is also proper pursuant to 28 U.S.C. §§ 1391(b) and (d) and 1400(b) because, upon information and belief, various acts and transactions constituting at least a substantial portion of some of the counterclaims arose in this judicial district.

#### THE PARTIES

- 8. Mindray USA is a Delaware corporation having its principal place of business at 800 MacArthur Blvd., Mahwah, NJ 07430.
- 9. Masimo purports to be a Delaware corporation with its principal place of business at 40 Parker, Irvine, California 92618.

# ALLEGATIONS COMMON TO ANTITRUST, UNFAIR COMPETITION, TORTIOUS INTERFERENCE, AND PATENT INFRINGEMENT COUNTERCLAIMS

## A. Background of Pulse Oximetry

- 10. Pulse oximetry involves the noninvasive measurement of oxygen levels in a patient's blood. This is accomplished by using a system generally comprising a sensor, a monitor and a patient cable that connects the sensor to the pulse oximeter monitor. The sensor may be reusable or disposable and typically is applied onto the finger of an adult patient or the foot of an infant. Special purpose sensors also may be used on other parts of the body, such as the ear and the forehead.
- 11. A basic pulse oximeter sensor contains two light-emitting diodes ("LEDs") one red and one infrared. The LEDs emit light that passes through the patient's tissue, and a receptor generally opposite the LEDs detects the amount of light that is not absorbed by the blood and tissue. This information is transmitted from the sensor via the patient cable to the pulse oximeter monitor. The pulse oximeter monitor may be a standalone pulse oximeter monitor that reports pulse rate, blood oxygenation saturation ("SpO2") and a plethysmographic waveform (a waveform that shows the time-varying changes in blood volume in the tissue), or alternatively, a multi-parameter patient parameter monitor ("MPPM") that includes sensors that measure and report other patient parameters, such as ECG, blood pressure, etc.
- 12. Because oxygenated blood absorbs light differently than deoxygenated blood, the monitor is able to use various well-known algorithms to calculate oxygenation saturation of the blood in the tissue based on light absorption, as well as additional patient parameters, such as pulse rate. On information and belief, pulse oximetry was invented in the 1970s and introduced

into the United States healthcare markets during the early 1980s, long before Masimo's existence.

- 13. Pulse oximeter monitors are comprised of electronic circuitry and software. The monitors are reusable, durable pieces of equipment that typically function from 5 to 10 years before being replaced. Pulse oximeter monitors or "pulse oximeters" typically are sold as either standalone devices or components of a multi-parameter patient monitoring system ("MPPM").
- 14. Patient cables and sensors are commodity products that must be replaced frequently. Hospitals generally purchase either disposable sensors, which must be replaced after each use, or reusable sensors, which typically are replaced every 1 to 2 years. Likewise, patient cables typically have a limited useful life of about a year.

#### **B.** The Relevant Markets

- 15. There is a relevant product market for pulse oximeter monitors. The relevant geographic market for this product is the United States. The pulse oximeter monitor market contains several relevant submarkets a market for stand-alone pulse oximeter monitors, a market for MPPM monitors, and an underlying technology market (OEM circuit boards, as set forth below). There is virtually no cross-elasticity of demand between pulse oximeter monitors and other forms of obtaining blood oxygen saturation, such as invasive methods of analyzing blood oxygen saturation via analysis of periodic blood draws.
- 16. There is a second relevant product market for pulse oximetry sensors. Absent anti-competitive constraints, customers would make buying decisions for less expensive and more durable sensors independently from decisions to purchase pulse oximeter monitors. The relevant geographic market for this product is the United States. There is no cross-elasticity of demand between sensors for non-invasive use with pulse oximeter monitors and sensors used in connection with invasive methods of obtaining blood oxygen saturation via analysis of periodic blood draws.
- 17. There is a third relevant product market for patient cables used to connect sensors to pulse oximeter monitors. Absent anti-competitive constraints, customers would make buying

decisions for less expensive and more durable patient cables independently from decisions to purchase pulse oximeter monitors. The relevant geographic market for this product is the United States. There is no cross-elasticity of demand between patient cables for non-invasive use with pulse oximeter monitors and accessories used with invasive methods of obtaining blood oxygen saturation via analysis of periodic blood draws.

- Masimo markets pulse oximeters under the brand name "Masimo SET®."

  Masimo manufactures its own pulse oximeter monitors but also has licensed its technology to third parties in the form of circuit boards that include the "Masimo SET®" pulse oximeter functionality ("OEM circuit boards"). These third parties, including Nellcor Puritan Bennett LLC (a subsidiary of Covidien Inc.), Philips Medical Systems (part of Royal Philips Electronics), and Mindray DS USA, Inc. (prior to 2008, Datascope Corporation), manufacture pulse oximeter monitors pursuant to their agreements with Masimo. On information and belief, Nellcor is currently the largest manufacturer of Masimo-licensed pulse oximeters, which are sold under the brand name "Oximax." In addition, Masimo sells OEM circuit boards for incorporation into MPPMs.
- 19. Mindray USA has made, imports, and sells Masimo-branded SET® circuit boards incorporated into its BeneView pulse oximeters and MPPMs. Mindray USA also has made, imports and sells pulse oximeter monitors that use pulse oximetry algorithms developed by Shenzhen Mindray Bio-Medical Electronics Co., Ltd. ("Shenzhen Mindray"). Mindray USA has its monitors made by, and purchases such monitors in China from, Shenzhen Mindray, and Mindray USA then imports, sells and distributes such monitors in the United States.
- 20. The relevant market for pulse oximeter monitors (including standalone pulse oximeter monitors, MPPMs and OEM circuit boards) is highly concentrated. On information and belief, Masimo currently controls over 80% of the market by manufacturing its own products and by directing the competitive activities of its licensees and distributors. The market for pulse oximeter monitors is also subject to high barriers to entry, including the cost of developing intellectual property and defending against lawsuits.

- 21. The markets for sensors and patient cables are moderately concentrated with lower barriers to entry due to the commodity nature of both products and relatively low technical hurdles to production.
- 22. Sensor and patient cable sales account for significantly more revenue than sales of pulse oximeter monitors in any given year. For companies like Masimo and Mindray USA, the primary driver for sales of sensors and patient cables is an installed base of pulse oximeter monitors (including standalone pulse oximeter monitors, MPPMs and third-party monitors that incorporate Masimo OEM circuit boards). On information and belief, more than 80% of Masimo's revenues are derived from forcing Masimo pulse oximeter monitor customers to purchase Masimo sensors and patient cables, to the exclusion of other competitors in the United States, including Mindray USA.

## C. Masimo's Market Power

- 23. Masimo has engaged in a systematic effort to monopolize pulse oximetry in the United States and that effort has caused irreparable damage and distortion to the pulse oximetry market in the United States, resulting in supracompetitive prices for pulse oximetry products and exclusion of competitors, to the ultimate harm of the market participants, including Mindray USA, and consumers. Masimo's systematic efforts to monopolize the pulse oximetry markets in the United States have forced existing companies in the field of pulse oximetry to convert to Masimo SET® or face disruptive and debilitating lawsuits, and have threatened and disrupted the ability of new entrants to gain a substantial foothold, such that the pulse oximetry field as a whole has stagnated, with virtually no innovation for more than a decade. Masimo's efforts to monopolize have directly injured Mindray USA's ability to introduce safe, effective, lower-cost, durable pulse oximetry products into the relevant markets in the United States, have injured consumers in the United States market, and have affected the United States market, by causing supracompetitive prices and exclusion of competitors, depriving consumers of alternative safe, effective, low-cost and durable pulse oximetry products.
- 24. Masimo currently wields market power in the sale of pulse oximeter monitors, sensors and patient cables in the United States. It has the ability to control price and exclude competition in the United States, and routinely exercises those powers, with direct, foreseeable and substantial effect on domestic commerce in the United States and United States import trade. In exercising those powers, Masimo has illegally threatened and interfered with Mindray USA's ability to compete in the relevant market and submarkets in the United States, and caused supracompetitive prices for Masimo and Nellcor branded or compatible pulse oximetry sensors and patient cables thereby causing threatened and actual antitrust injury to Mindray USA's business and property by being excluded from the United States market for pulse oximetry products and by paying supracompetitive prices for Masimo and Nellcor branded or compatible pulse oximetry sensors and patient cables that it purchases, thereby suffering actual losses and overcharges, lost sales and profits. Masimo's market power extends equally into the

corresponding submarkets for standalone pulse oximeter monitors, MPPM monitors, OEM circuit boards, and the markets for pulse oximeter sensors and patient cables. Masimo's market power is maintained through the coordinated direction of its own branded products and its licensed pulse oximeter products.

- 25. Masimo's market power is derived in part from the abuse of its technology position, in part from its decade-long campaign of anti-competitive licensing strategies, and its abuse of the United States patent system, and in particular, patent continuation application practice as permitted in the United States.
- 26. Masimo has entered into numerous contracts to restrain competition for the sale of pulse oximeter technology by third parties in the United States. Masimo exerts control over the United States market by dictating the terms under which licensees or distributors can compete using their own branded pulse oximeter monitors or Masimo-branded pulse oximeter monitors. Masimo's anti-competitive contracting policies have affected the United States market by causing supracompetitive prices and exclusion of competitors, and have directly harmed Mindray USA by being excluded from the United States market for pulse oximetry products and by paying supracompetitive prices for Masimo and Nellcor branded or compatible pulse oximetry sensors and patient cables that it purchases, and by limiting Mindray USA's ability to offer and sell safe, effective, low-cost, durable pulse oximetry products using non-Masimo pulse oximetry technology in the United States, thereby causing antitrust injury through actual losses and overcharges, lost sales and profits.to Mindray USA's business and property.
- 27. Upon information and belief, Masimo's licensing agreements usually demand that its licensees promote Masimo SET® as their primary pulse oximetry technology. In many of its licenses, Masimo requires the licensee to abandon marketing or sales of its own pre-existing pulse oximetry technology and forego development of any competing technology. Through its agreements and technically useless and exclusionary changes to its OEM circuit boards, Masimo has directed licensees and distributors to exclude competition in the pulse oximeter monitor, sensor, and patient cable markets in the United States. Masimo extracts the anti-competitive

profits from these exclusionary practices by recovering royalties for the sale of both patented and unpatented goods. As a result of Masimo's technically useless tying arrangements, detailed *supra*, Mindray USA has paid overcharges for Masimo and Nellcor branded or compatible pulse oximetry sensors and patient cables that it purchases, and has been hampered in its ability to compete in the relevant markets in the United States by offering and selling safe, effective, low-cost, durable pulse oximetry products using non-Masimo pulse oximetry technology, thereby causing antitrust injury to Mindray USA's business and property.

- 28. Through the combination of its direct pulse oximeter monitor and accessory sales and its control over third-party pulse oximeter monitor manufacturers, Masimo has become the single dominant firm in the market for pulse oximeter monitors, including the submarkets for standalone pulse oximeter monitors, MPPM monitors, OEM circuit boards, and in the market for sensors and patient cables. Masimo's dominant market position empowers it to control pricing and exclude competition in the United States from non-Masimo pulse oximetry technology, including competing pulse oximetry technology offered by Mindray USA's OEM supplier, Shenzhen Mindray.
- 29. As detailed below, Masimo has created and maintained its unlawful monopoly position through various unlawful anti-competitive practices. Masimo has further exploited its unlawful monopoly position in the United States market for pulse oximeter monitors to capture additional profits from the relevant markets for patient cables and sensors. As detailed below, Masimo's unlawful and anti-competitive exclusionary practices include the following:
  - Exclusionary exclusive dealing agreements and licenses with competitors and distributors;
  - Exclusionary technological interfaces used to unlawfully tie and condition the use of Masimo sensors and patient cables to the use of Masimo pulse oximeter monitors;
  - c) Exclusionary pricing and bundling practices; and

- d) Exclusionary inequitable conduct and actual and attempted enforcement of the invalid and unenforceable '222, '986, '958, '154, '194 and '952 patents.
- 30. As a result of Masimo's anticompetitive conduct and exclusionary practices, the United States market for pulse oximetry products has been unlawfully affected, leading to supracompetitive prices for pulse oximetry products and the exclusion of competitors.
- 31. As a result of Masimo's anticompetitive conduct and exclusionary practices, Mindray USA has suffered threatened and actual antitrust injury to its business and property by being excluded from offering competing pulse oximetry technology in the United States market, and by paying supracompetitive prices for Masimo and Nellcor branded or compatible pulse oximetry sensors and patient cables that it purchases thereby suffering actual losses and overcharges, lost sales and profits.
  - 32. As a result of the foregoing, Mindray USA asserts the following claims for relief:
    - a) Monopolization (Counterclaim 1);
    - b) Attempted monopolization (Counterclaim 2 and Counterclaim 3);
    - c) Conspiracy to monopolize (Counterclaim 4);
    - d) Tying (Counterclaim 5)
    - e) Group boycott (Counterclaim 6);
    - f) Agreement in restraint of trade (Counterclaim 7);
    - g) Walker Process monopolization claim (Counterclaim 8;
    - h) Walker Process attempted monopolization claim (Counterclaim 9);
    - i) Tortious interference with contract (Counterclaim 10); and
    - j) Statutory unfair competition under California Business & Professions
       Code §17200(Counterclaim 11).
    - D. Exclusionary Agreements with Competitors and
      Distributors
- 33. Masimo has forced many of its current and former competitors to enter into exclusive dealing arrangements under threat of onerous patent litigation. These agreements

require the licensee or distributor to produce and sell primarily Masimo branded pulse oximeter monitors, patient cables, or sensors, and to abandon such licensee's competing pulse oximetry technologies. These agreements either expressly prohibit the sale of non-Masimo pulse oximeter monitors, patient cables, or sensors, or create a threat of patent litigation for continued sale of non-Masimo pulse oximeter monitors, patient cables and sensors, even if the non-Masimo products would not infringe any of Masimo's patents. Masimo has compounded the anti-competitive effect of such license provisions by demanding that its licensees forego challenges to the validity of Masimo's patents to retain the license, a provision that is facially unenforceable.

- 34. Masimo has further engaged in anti-competitive conduct in unreasonably interpreting its licenses to have extra-territorial effect. The foregoing conduct has affected the United States market by causing supracompetitive prices and exclusion of competitors. All of the foregoing provisions have harmed Mindray USA's ability to compete in the relevant markets for pulse oximetry products in the United States by paying supracompetitive prices for Masimo and Nellcor branded or compatible pulse oximetry sensors and patient cables that it purchases and by preventing Masimo licensees, such as Mindray USA, and distributors from adopting, selling and distributing safe, effective, low-cost, durable pulse oximetry products in the United States based on non-Masimo pulse oximetry technology, thereby causing injury to Mindray USA's business and property through actual losses and overcharges, lost sales and profits.
- 35. Masimo's licensing and distribution agreements have foreclosed significant commerce in the United States market for pulse oximeters by preventing the sale or introduction of competing products. In addition, the licensing and distribution agreements have stifled the incentive to innovate, as a large percentage of distributors are unable to offer a competing non-Masimo pulse oximeter monitor even where it can be sold at a lower price or with superior features. The licensing and distribution agreements also preclude the sale of unpatented competing patient cables and sensors for use with Masimo pulse oximeter monitors in the United States, even though these are commodity products for which Masimo would otherwise face

competition from a variety of branded and generic products, including products available to Mindray USA from its OEM supplier, Shenzhen Mindray.

- 36. Masimo has also entered into agreements prohibiting the promotion of competing products, regardless of whether such products might offer better quality or more competitive prices to customers. In some cases Masimo has required its licensees and distributors to discontinue sales of competing products in the United States. For example, Masimo has forced Mindray USA to discontinue purchases of Mindray SpO2 from Shenzhen Mindray, which has a direct and immediate effect on domestic United States commerce and United States import trade for those customers no longer able to obtain Mindray USA pulse oximetry products using Mindray SpO2 pulse oximetry technology.
- 37. Masimo has also required licensees and distributors to agree not to offer any competing pulse oximeter monitors at a lower price than Masimo's SET® pulse oximeter monitor, even if customers would benefit from differentiated pricing.
- 38. As of 2011, according to its public statements, Masimo had licensing or distribution agreements with 53 OEM partners, which accounted for over 90% of the worldwide shipments of pulse oximeter monitors. On information and belief, Masimo systematically requires its licensees and partners to agree to provisions designed to exclude competition in the United States. Such provisions can be found in current and former agreements with Mindray USA, Respironics, Medical Data Electronics, Invivo, Shenzhen Mindray, Royal Philips Medical Systems and others.
- 39. Masimo also has engaged in unfair and anti-competitive conduct by threatening to disrupt its agreements with existing licensees unless those licensees require affiliated OEM manufacturers also to make Masimo the primary pulse oximetry technology of such OEM manufacturers. Masimo's unlawful exclusionary practices have injured both Mindray USA and its customers, and have had a direct and substantial effect on domestic commerce in, and import trade to, the United States.

- 40. Masimo's exclusionary licensing and distribution provisions are specifically designed and intended to stabilize the market and exclude competition in the United States, including competition from Mindray USA. Such conduct has a direct, substantial, and reasonably foreseeable effect on United States commerce and import commerce.
- 41. Masimo's exclusionary licensing and distribution provisions have harmed competition in the United States market by causing supracompetitive prices and exclusion of competitors. For example, as a result of Masimo's exclusionary license provisions, Mindray USA has, except for repair or service, discontinued purchase, importation and sale of Shenzhen Mindray pulse oximeter monitors that employ Mindray-based pulse oximetry technology, as well as pulse oximeter sensors and patient cables for use with such oximeters.
- 42. In addition or in the alternative, Masimo's exclusionary licensing and distribution provisions have directly harmed Mindray USA's activities as alleged by Masimo, blocking Mindray USA from importing, selling or offering for sale pulse oximetry products in the United States. Masimo's exclusionary licensing and distribution tactics, which unlawfully restrict Mindray USA from carrying non-Masimo pulse oximeter monitors, have caused antitrust injury to Mindray USA, and have caused antitrust injury to Mindray USA's business and property in the United States, among other things, by paying supracompetitive prices for Masimo and Nellcor branded or compatible pulse oximetry sensors and patient cables that it purchases, and by hurting sales and imports of Mindray USA, and other non-Masimo pulse oximetry products, in and to the United States.
- 43. Mindray USA consumers throughout the United States, and all other consumers of pulse oximeter products, including consumers located in the State of New Jersey, have been harmed by Masimo's exclusionary licensing and distribution provisions which have reduced customer choice, restrained output, and raised prices and have affected the United States market by causing supracompetitive prices and exclusion of competitors. As a direct result of Masimo's exclusionary licensing and distribution provisions and of the harmful effects of those provisions in the United States, distributors and importers cannot offer, or have discontinued offering,

Mindray USA sensors and patient cables in the United States, or competitive third-party sensors and patient cables available from Mindray USA's OEM supplier, Shenzhen Mindray, including to customers within the State of New Jersey, thereby causing injury to Mindray USA's business and property, by being excluded from the United States market for pulse oximetry products and by paying supracompetitive prices for Masimo and Nellcor branded or compatible pulse oximetry sensors and patient cables that it purchases, thereby suffering actual losses and overcharges, lost sales and profits.

## **E.** Exclusionary Technological Interfaces

- 44. Prior to 2009, Masimo pulse oximeter monitors and pulse oximetry sensors employed a proprietary interface called "ProCal." The ProCal interface comprised a patented resistor resident in Masimo's sensor, together with software programming in the pulse oximeter monitor that detected the presence of the resistor once upon insertion of the patient cable and again prior to rendering a measurement. Masimo's pulse oximeter monitors (including standalone monitors, MPPMs and OEM circuit boards) were programmed not to function unless they detected the presence of a Masimo branded sensor containing ProCal.
- 45. Beginning in 2009, Masimo changed its pulse oximeter monitors and OEM circuit boards to include its latest patented and exclusionary technology, called "X-Cal." Upon information and belief, X-Cal consists of an electronic memory device, such as an electrically programmable memory ("EPROM") disposed in a sensor/patient cable that is checked each time the sensor is connected to the pulse oximeter monitor. The pulse oximeter monitor reads identifying information for the connected sensor/patient cable, including how long the sensor/patient cable has been in use and compares that information to a threshold. If the pulse oximeter monitor detects that the sensor/patient cable lacks the identifying information, or that usage has exceeded the threshold, the pulse oximeter rejects the sensor/patient cable and does not work. This in turn requires the hospital or care-giver to replace the rejected sensor/patient cable with a new Masimo unit.

- 46. Upon information and belied, Masimo began requiring its licensees and distributors, including Mindray USA's OEM supplier, Shenzhen Mindray, to re-engineer their pulse oximeter monitors to accept Masimo OEM circuit boards that include the X-Cal technology, which circuit boards are incompatible with earlier versions of Masimo OEM circuit boards.
- 47. According to public information, while Masimo originally included its X-Cal technology in reusable components, beginning in 2011, Masimo also incorporated its X-Cal technology into its disposable sensors.
- 48. Masimo's ProCal and X-Cal interfaces have a direct, substantial, and reasonably foreseeable harmful effect on United States commerce and import commerce by excluding causing supracompetitive prices on pulse oximeter products and excluding competitors, including Mindray USA in both the sensor and patient cable markets throughout the United States, including the market for such products in the State of New Jersey. In short, Masimo's ProCal and X-Cal interfaces make it so that Masimo's pulse oximeter monitors (including standalone monitors, MPPMs and OEM circuit boards) will not work with non-Masimo branded sensors. Because Masimo dominates the United States market for pulse oximeter monitors, Masimo's technology, which prevents non-Masimo sensors from being used with Masimo monitors restricts customer choice, restrains output, and raises prices for pulse oximetry sensors. Such conduct causes antitrust injury to Mindray USA's business and property by suffering actual losses and overcharges, lost sales and profits..
- 49. On information and belief, there is no technical need to nest a ProCal resistor in parallel with the LEDs or to insert an X-Cal memory device in the sensor/patient cable. The purpose of these interfaces is to create a technological tie between the Masimo pulse oximeter monitor and Masimo sensors and patient cables. As a result of ProCal and X-Cal, Masimo sensors are the only sensors that will function with Masimo pulse oximeters. Any competing sensor is rejected.

- 50. On information and belief, the further purpose of Masimo's X-Cal interface is to require the hospital or care-giver to discard the sensor/patient cable and to purchase a new sensor or patient cable from Masimo long before the useful life of the sensor or patient cable has been attained. The X-Cal interface not only ties the customer to using Masimo sensors and patient cables with its Masimo pulse oximeter monitors, but requires the customer to replace such sensors and patient cables more frequently than required if the sensor or patient cable omitted that interface. Masimo's X-Cal interface prohibits competition from lower-cost, more durable pulse oximeter sensors and patient cables. Masimo's exclusionary X-Cal interface has harmed competition in the United States and has affected the market by causing supracompetitive prices and exclusion of competitors, including Mindray USA, by, among other things restricting consumer choice, restraining output, and raising prices with respect to pulse oximeter sensors. This conduct has caused antitrust injury to Mindray USA's business and property by being excluded from the United States market for pulse oximetry products and by paying supracompetitive prices for Masimo and Nellcor branded or compatible pulse oximetry sensors and patient cables that it purchases, thereby suffering actual losses and overcharges, lost sales and profits..
- 51. But for Masimo's tying, non-Masimo sensors and patient cables, including sensors and patient cables available to Mindray USA from its OEM supplier, Shenzhen Mindray, would function with a Masimo pulse oximeter monitor, just as non-Masimo sensors and patient cables routinely function with non-Masimo pulse oximeter monitors, including non-Masimo pulse oximeter monitors sold by Mindray USA.
- 52. On information and belief, Masimo has designed its ProCal and X-Cal interfaces to "lock in" customers to Masimo products with anti-competitive effect in the United States. Masimo's ProCal and X-Cal ties have the effect of increasing changeover costs and raising barriers to entry for competitors. Masimo has employed the ProCal and X-Cal interfaces with the specific intent to foreclose competition and, among other things, to limit the ability and opportunity of customers to switch to competing pulse oximetry products, including those

available from Mindray USA's OEM supplier, Shenzhen Mindray, and other competitors to Masimo, in the United States. The X-Cal interface has the further direct, substantial, and reasonably foreseeable effect of eliminating competition in the United States, with respect to more durable sensors and patient cables available from other competitors, including Mindray USA, by requiring customers to replace such sensors and patient cables while they are still perfectly functional. As a result, Masimo's X-Cal and ProCal ties, and the effects of those ties in the United States, have caused antitrust injury to Mindray USA's business and property, by being excluded from the United States market for pulse oximetry products and by paying supracompetitive prices for Masimo and Nellcor branded or compatible pulse oximetry sensors and patient cables that it purchases, and to Mindray USA's customers, other competitors to Masimo, and consumers.

- 53. On information and belief, Masimo requires its licensee Nellcor to use a similar method of tying with its Oximax pulse oximeter monitors. In 2006, Masimo prevailed in a lawsuit alleging that Nellcor pulse oximeters infringed certain claims of Masimo patents. The result of the litigation was Masimo's 2006 Settlement Agreement with Nellcor and subsequent amendments to that agreement, including the Second Amendment to Settlement Agreement and Release of Claims, which has an effective date of March 2011. Under the terms of the Settlement Agreement and subsequent amendments, including the 2011 Second Amendment, Nellcor is permitted to continue its sale of allegedly infringing pulse oximetry technology under the express condition that it pay a royalty on the revenues derived from all Nellcor oximetry products, including pulse oximeter monitors, sensors, and patient cables that were not subject to the infringement allegations. The agreement and the subsequent amendments thereto contemplate that Nellcor will use a "lock and key" mechanism to ensure that Nellcor ties its pulse oximeter monitors to aftermarket sales of sensors and patient cables in the United States.
- 54. Masimo has taken acts in furtherance of its conspiracy in the past four years, and continues to take such acts, by enforcing the Nellcor tying scheme through a covenant not to sue that is expressly nullified if Nellcor manufactures pulse oximeter monitors that are compatible

with any third-party (i.e., non-Nellcor) sensors. Masimo has taken additional steps to broaden the hold of its tying scheme by amending its covenant not to sue as recently as 2011. Masimo has used and continues to use, including within the limitations period, this provision to unlawfully exclude third-party sensor and patient cable manufacturers and to collect profits on sales of tied sensors and patient cables in the United States.

- 55. Nellcor's sensors are tied to its Oximax pulse oximeter monitors through a technological "lock and key" protocol known as DigiCal. But for this tying arrangement, non-Nellcor sensors and patient cables would function with a Nellcor pulse oximeter monitor, just as non-Nellcor sensors and patient cables routinely function with non-Nellcor pulse oximeter monitors, including pulse oximeters manufactured by competitors including Shenzhen Mindray.
- Nellcor to use the DigiCal interface to "lock-in" customers with Nellcor products. This requirement directly benefits Masimo by artificially increasing sales of Nellcor sensors and patient cables, on which Masimo collects a high royalty based on its agreement with Nellcor. DigiCal technology is not available to Mindray USA other than in connection with sale or resale of Nellcor products. Masimo has required, and continues to require, the use of DigiCal with the specific intent to foreclose competition in the relevant market for pulse oximetry, including the submarkets for pulse oximeter monitors, sensors and patient cables in the United States and, among other things, to limit the ability and opportunity of customers to switch to competing pulse oximetry products, including those offered by Mindray USA.
- 57. By forcing, and continuing to force within the last four years, Nellcor to tie its sensors to its pulse oximeters, Masimo has been able and continues to extract anti-competitive profits from Nellcor's substantial installed base of pulse oximeter monitor customers in the United States, while blocking competitors, such as Mindray USA, from making, importing, selling or offering for sale competing products in the United States. By collecting anti-competitive profits from all oximetry products, including current and future products that do not infringe Masimo's patents, Masimo effectively forecloses, and continues to foreclose, Nellcor

from any effort to invent around Masimo's technology.

- 58. Masimo requires its licensees who use Masimo OEM circuit boards to similarly tie customers to Masimo's ProCal and X-Cal interfaces. Masimo's license agreements prohibit its licensees from offering pulse oximeter sensors or patient cables that can be used with the Masimo OEM circuit boards, thus ensuring that its licensees tie their Masimo-based pulse oximeter monitors to aftermarket sales of Masimo sensors and patient cables in the United States. This Masimo practice also prevents competitors, such as Mindray USA, from making or selling compatible sensors in the United States.
- 59. Masimo enforces its tying scheme against licensees by threats to terminate its license if a licensee manufactures Masimo-based pulse oximeter monitors that are compatible with any third-party (i.e., non-Masimo) sensors or patient cables. Masimo uses such provisions to exclude third-party sensor and patient cable manufacturers and to collect profits on sales of tied sensors and patient cables.
- 60. By forcing its licensees to tie their pulse oximeter monitors to Masimo sensors and patient cables, Masimo is able to extract anti-competitive profits from such licensees' installed base of pulse oximeter monitor customers in the United States, and to ensure that such customers are locked into using Masimo pulse oximetry technology for the foreseeable future. By collecting anti-competitive profits from all licensee-based oximetry products, including current and future products that do not infringe Masimo's patents, Masimo effectively forecloses any effort to invent around Masimo's technology.
- All of the pulse oximeter monitors to Nellcor and Masimo sensors and patient cables, Masimo has caused, and continues to cause, direct, substantial and foreseeable harm to the United States market by causing supracompetitive prices and exclusion of competitors. This conduct has caused antitrust injury to Mindray USA's business and property by being excluded from the United States market for pulse oximetry products and by paying supracompetitive prices for Masimo and Nellcor branded or compatible pulse oximetry sensors and patient cables that it purchases, thereby suffering actual losses and

overcharges, lost sales and profits. The direct, substantial, and reasonably foreseeable effect of Masimo's conduct in furtherance of its conspiracy in the last four years is to foreclose Mindray USA from offering competing sensors and patient cables to customers throughout the United States, including within the State of New Jersey.

- 62. Mindray USA also is directly harmed by Masimo's conduct in that it is prevented from engaging in the importation, sale and offer for sales in the United States of compatible sensors and cables, and pays supracompetitive prices for pulse oximetry sensors and patient cables that it purchases, which causes antitrust injury to Mindray USA's business and property by being excluded from the United States market for pulse oximetry products and by paying supracompetitive prices for Masimo and Nellcor branded or compatible pulse oximetry sensors and patient cables that it purchases, thereby suffering actual losses and overcharges, lost sales and profits. Masimo's conduct, and the effects of that conduct in the United States, has injured and continues to injure Mindray USA's business and property by, among other things, hurting sales and imports of Mindray USA, and other non-Masimo sensor and patient cable products, in and to the United States.
- 63. Masimo's forcing of Nellcor and Masimo licensees to tie their pulse oximeter monitors to Nellcor and Masimo sensors and patient cables have injured, and continue to injure, the domestic commerce, import trade and consumers in the United States, including in New Jersey. Among other things, Masimo's foreclosure of the use of non-Masimo or Nellcor sensors and patient cables has reduced customer choice, restrained output, and raised prices.

## F. Exclusionary Pricing and Bundling Practices

- 64. Sensors and patient cables are consumables that must be frequently replaced, often after a single use. As a result, hospitals must keep a stock of sensors and patient cables on hand at all times.
- 65. Masimo has engaged in exclusionary predatory and below cost pricing and bundling practices designed to lock United States hospitals into Masimo pulse oximetry products, and to prevent such hospitals from buying products from competitors including

Mindray USA, its distributors and affiliates. On information and belief, Masimo has induced certain hospitals to convert to Masimo SET® by offering pulse oximeter monitors at no cost in exchange for a commitment to purchase a minimum number of sensors over the course of a long-term contract, typically five to ten years. After the long-term contract expires, Masimo continues to lock in the customer through its tying of patient cables and sensors to its pulse oximeter monitors.

- 66. On information and belief, Masimo's anti-competitive pricing and bundling practices are designed to shift hospital capital costs to consumers and third-party payers, who are charged a premium over the price of the commodity consumable sensors. These practices injure domestic commerce and import trade into the United States by excluding competitors, and have a direct, substantial and foreseeable effect on consumers and Masimo's competitors, including Mindray USA.
- 67. Once a hospital standardizes on Masimo oximetry products, additional purchases of Masimo pulse oximeter monitors and sensors are mutually reinforcing. A hospital using Masimo pulse oximeter monitors must maintain a large stock of Masimo sensors and patient cables due to technological ties that prohibit compatibility with competing sensors. This stock creates a strong economic incentive for the hospital to purchase only Masimo pulse oximeter monitors and discourages the hospital from changing to a competing non-Masimo pulse oximeter technology, such as Mindray SpO2, offered by Mindray USA. To do otherwise would require the hospital to maintain separate stocks of sensors and patient cables for its Masimo and non-Masimo pulse oximeter monitors, increasing overall costs.
- 68. Masimo's requirement that Nellcor tie its sensors to its pulse oximeter monitors similarly creates a strong economic incentive for Nellcor's United States hospital customers to purchase only Nellcor pulse oximeter monitors. To do otherwise would require the hospital to maintain separate stocks of sensors and patient cables for its Nellcor and non-Nellcor pulse oximeter monitors, increasing overall costs.

- 69. Masimo's conduct has had a direct, substantial and foreseeable effect on domestic United States commerce and import trade in the United States, including within the State of New Jersey by causing supracompetitive prices and excluding competitors. Its anti-competitive pricing and bundling practices preclude future competition by locking up prospective customers and raising barriers to entry. Masimo's scheme is designed to preserve market power by depriving customers of product choice and competitive prices in pulse oximetry. Its X-Cal interface further deprives customers from switching to more durable, less expensive non-Masimo sensors and patient cables. These practices have directly caused antitrust injury to Mindray USA's business and property in the United States and that of Mindray USA's customers in the United States.
- 70. Masimo's licensing, pricing, bundling practices and tying schemes have caused antitrust injury and continue to cause antitrust injury to Mindray USA's business and property in the United States by being excluded from the United States market for pulse oximetry products and by paying supracompetitive prices for Masimo and Nellcor branded or compatible pulse oximetry sensors and patient cables that it purchases, thereby suffering actual losses and overcharges, lost sales and profits.. Masimo's conduct has had the direct, substantial, and reasonably foreseeable effect of precluding hospitals throughout the United States, and within the State of New Jersey, from choosing Mindray USA's pulse oximetry products based on non-Masimo pulse oximetry technology, which are both more durable and could be offered less expensively than those of Masimo. As a result of Masimo's conduct in the last four years, as well as its continuing conduct, and the effects of that conduct in the United States, Mindray USA has lost sales of Mindray-based pulse oximeter monitors and has been precluded from selling its own sensors and patient cables to hospitals using Masimo SET® or Nellcor Oximax pulse oximetry technology and has paid supracompetitive prices for Masimo and Nellcor branded or compatible pulse oximetry sensors and patient cables that it purchases.

# ADDITIONAL ALLEGATIONS RELATING TO MASIMO'S BASELESS ASSERTION OF PATENT INFRINGEMENT CLAIMS AGAINST MINDRAY USA AND SHENZHEN MINDRAY

- 71. Masimo previously threatened Mindray USA with suit for alleged infringement of nine U.S. patents in an action entitled *Masimo Corporation v. Shenzhen Mindray Bio-Medical Electronics Co., Ltd.*, Case No. SACV12-02206 CJC (JPRx), currently pending in the United States District Court for the Central District of California, Santa Ana Division ("the California litigation").
- 72. The patents previously asserted against Mindray USA, and still being asserted against Shenzhen Mindray in the California litigation are as follows (collectively, "Masimo's asserted patents"):
  - U.S. Patent No. 6,002,952, entitled "Signal Processing Apparatus and Method" (" '952 patent");
  - U.S. Patent No. 6,263,222, entitled "Signal Processing Apparatus" ("the '222 patent");
  - U.S. Patent No. 6,580,086, entitled "Shielded Optical Probe and Method" ("the '086 patent");
  - U.S. Patent No. 6,699,194, entitled "Signal Processing Apparatus and Method" ("the '194 patent");
  - U.S. Patent No. 6,745,060, entitled "Signal Processing Apparatus" ("the '060 patent");
  - U.S. Patent No. 7,215,986, entitled "Signal Processing Apparatus" ("the '986 patent");
  - U.S. Patent No. 7,489,958, entitled "Signal Processing Apparatus and Method" ("the '958 patent");
  - U.S. Patent No. 7,509,154, entitled "Signal Processing Apparatus" ("the '154 patent"); and

- U.S. Patent No. 8,229,533, entitled "Low-Noise Optical Probes For Reducing Ambient Noise" ("the '533 patent").
- 73. Masimo's asserted patents continue to be asserted by Masimo against Shenzhen Mindray in the California litigation for manufacturing the Mindray USA pulse oximeter products that incorporate Shenzhen Mindray SpO2 algorithms, which Masimo alleges constitutes a breach of the DS Agreement.
- 74. Mindray USA's sale, offer for sale, importation and distribution of pulse oximeter products incorporating Shenzhen Mindray SpO2 algorithms are licensed under the DS Agreement, and none of those products infringe any of Masimo's asserted patents in the California litigation.

#### ADDITIONAL ALLEGATIONS RELATING TO PATENT MISUSE

- 75. Upon information and belief, in November 2002, Masimo entered into a contract with Shenzhen Mindray relating to integration by Shenzhen Mindray of OEM Circuit boards containing Masimo SET® pulse oximetry technology into Shenzhen Mindray pulse oximeter monitors ("the 2002 Agreement").
- 76. Upon information and belief, the 2002 Agreement called for Shenzhen Mindray to promote sales of Masimo SET® pulse oximetry technology in China and outside the United States, and for Masimo to provide technical and marketing support to Shenzhen Mindray.
- 77. Upon information and belief, by 2008, Masimo had ceased providing support to Mindray USA to promote sales of Masimo SET® pulse oximetry technology in China. Upon information and belief, in 2009, Masimo informed Shenzhen Mindray that it had discontinued the model of OEM circuit board supplied to Shenzhen Mindray, and required Shenzhen Mindray to redesign its Masimo-equipped pulse oximeter monitors to implement the X-Cal interface.
- 78. Upon information and belief, Shenzhen Mindray customers in China had been complaining about the durability of Masimo's pulse oximeter sensors and patient cables since at least 2006, indicating a preference for Shenzhen Mindray pulse oximeter sensors and patient cables, which were less expensive and more durable.

- 79. Upon information and belief, Shenzhen Mindray invested considerable resources in re-engineering its pulse oximeter monitors to accept the X-Cal version of Masimo's OEM circuit boards. The limited lifetime of pulse oximeter sensors and patient cables equipped with the X-Cal interface required Shenzhen Mindray's customers to replace their pulse oximeter sensors and patient cables more frequently than had been the case for Shenzhen Mindray pulse oximeter monitors equipped with the non-X-Cal version of Masimo's OEM circuit board. Upon information and belief, the need to replace sensors even more frequently than before exacerbated the dissatisfaction of Shenzhen Mindray's Chinese customers, resulting in fewer sales of Shenzhen Mindray pulse oximeter monitors including Masimo SET® pulse oximetry technology.
- 80. Masimo's response to this decline in sales of OEM circuit boards was to demand that Shenzhen Mindray agree to buy larger quantities of Masimo OEM circuit boards for integration into pulse oximeter monitors to be sold in China. Masimo's demands that Shenzhen Mindray agree to increase the quantities of OEM circuit boards was commercially unreasonable under the circumstances.
- 81. In an effort to force Shenzhen Mindray to comply with its demands in China, Masimo made threats to Shenzhen Mindray to interfere with its commercial relationship with Mindray USA, Shenzhen Mindray's customer.
- 82. Upon information and belief, Masimo has been aware for many years that Mindray USA has sold small quantities of pulse oximeter monitors that do not use Masimo OEM circuit boards, or those of Masimo's licensee Nellcor. Upon information and belief, Masimo is further aware that these pulse oximeter monitors do not infringe any Masimo patent or in the alternative, has licensed such products under the DS Agreement.
- 83. Masimo has demanded that Mindray USA cease purchase and importation of pulse oximeter monitors, sensors and patient cables from Shenzhen Mindray that employ Shenzhen Mindray pulse oximeter technology. Upon information and belief, Masimo also has demanded, on similar threats of interference with Mindray USA's commercial relationship, that

Shenzhen Mindray comply with Masimo's demands to exclusively promote Masimo SET® in China and elsewhere outside the United States and abandon sales of Shenzhen Mindray's competing pulse oximeter technology in China and outside the United States.

84. Masimo has tied its anti-competitive threats against Mindray USA to Shenzhen Mindray's conduct in China and outside the United States, where Masimo has no relevant patents. Masimo's effort to secure an extra-territorial effect for its U.S. patents constitutes patent misuse that renders Masimo's patents unenforceable.

# ADDITIONAL ALLEGATIONS COMMON TO INEQUITABLE CONDUCT AND WALKER PROCESS ANTITRUST COUNTERCLAIMS

#### A. Background and Development of Masimo's Patent Portfolio

- 85. Upon information and belief, Masimo's patent portfolio is the culmination of a systematic and continuous decades' long effort by the officers of Masimo, and in particular Mr. Joe Kiani and Mr. Mohamed Diab, and their patent counsel, Knobbe, Martens, Olsen and Bear LLP to perpetrate fraud on the United States Patent and Trademark Office ("USPTO") and the American public by patenting inventions identically disclosed in the prior art, plainly suggested in the prior art, and/or first invented by others. Masimo and its patent counsel have cited hundreds, and occasionally, thousands of items of irrelevant prior art, during pendency of Masimo's patent applications, ostensibly under the guise of complying with their duty of candor under 37 C.F.R. 1.56. The true motive for such voluminous prior art citations, however, was to overwhelm the Patent Examiner in mountains of irrelevant prior art and thereby minimize the chance that the Patent Examiner would be able to locate the features of any relevant prior art reference.
- 86. As an integral part of that effort, Masimo and its counsel have abused the practice of filing continuation patent applications and continuation-in-part applications in the United States, by systematically engaging in prosecution laches. Continuation application practice is unique to the United States, and permits an inventor to file a patent application to seek additional claims in a patent application that were not obtained in an earlier application. A continuation-in-part application enables an applicant to add additional subject matter to a pending application while claiming an earlier priority date that typically forecloses the citation of prior art dated after the claimed priority date. Continuation applications and continuation-in-part applications are permitted nowhere outside of the United States.
- 87. Upon information and belief, Masimo currently holds title to more than 230 issued U.S. patents, most of which issued from continuation or continuation-in-part applications that claim priority to applications filed more than a decade ago. For example, according to the

United States Patent and Trademark Office website, Masimo has prosecuted, and continues to prosecute, more than thirty-eight (38) continuation applications that claim priority to U.S. patent application Serial No. 08/859,836, filed May 16, 1997, including:

- U.S. patent application Serial No. 08/887,815 filed on July 3, 1997;
- U.S. patent application Serial No. 10/185,804 filed on June 27, 2002;
- U.S. patent application Serial No. 09/110,542 filed on July 06, 1998;
- U.S. patent application Serial No. 09/195,791 filed on November 17, 1998; U.S. patent application Serial No. 09/199,744 filed on November 25, 1998; U.S. patent application Serial No. 09/996,921 filed on November 28, 2001; U.S. patent application Serial No. 10/005,631 filed on December 4, 2001; U.S. patent application Serial No. 10/062,859 filed on December 3, 2001; U.S. patent application Serial No. 10/062,859 filed on January 30, 2002; U.S. patent application Serial No. 10/677,050 filed on September 30, 2003; U.S. patent application Serial No. 10/676,534 filed on September 30, 2003; U.S. patent application Serial No. 10/676,534 filed on September 30, 2003; U.S. patent application Serial No. 10/838,593 filed on May 4, 2004;
- U.S. patent application Serial No. 10/838,814 filed on May 4, 2004;
- U.S. patent application Serial No. 11/003,231 filed on December 3, 2004; U.S. patent application Serial No. 11/070,081 filed on March 2, 2005;
- U.S. patent application Serial No. 11/154,093 filed on June 15, 2005;
- U.S. patent application Serial No. 11/432,278 filed on May 11, 2006;
- U.S. patent application Serial No. 11/533,286 filed on September 19, 2006; U.S. patent application Serial No. 11/754,238 filed on May 25, 2007;
- U.S. patent application Serial No. 11/766,700 filed on June 21, 2007;
- U.S. patent application Serial No. 11/766,714 filed on June 21, 2007;
- U.S. patent application Serial No. 11/766,719 filed on June 21, 2007;
- U.S. patent application Serial No. 11/842,117 filed on August 20, 2007;
- U.S. patent application Serial No. 11/894,716 filed on August 20, 2007;
- U.S. patent application Serial No. 12/047,274 filed on March 12, 2008;

- U.S. patent application Serial No. 12/047,286 filed on March 12, 2008;
- U.S. patent application Serial No. 12/277,221 filed on November 24, 2008; U.S. patent application Serial No. 12/410,422 filed on March 24, 2009;
- U.S. patent application Serial No. 13/370,239 filed on February 9, 2012;
- U.S. patent application Serial No. 13/397,564 filed on February 15, 2012; U.S. patent application Serial No. 13/397,579 filed on February 15, 2012; U.S. patent application Serial No. 13/402,782 filed on February 22, 2012; U.S. patent application Serial No. 13/463,746 filed on May 3, 2012; and U.S. patent application Serial No. 13/914,276 filed on June 10, 2013.

U.S. patent application Serial No. 08/859,837, to which the above patent family claims priority, was itself the fourth application in a chain of continuation and continuation-in-part applications claiming priority back to U.S. patent application Serial No. 07/666,060, filed on March 7, 1991. Including the three patents issued on the priority applications, the above chain of U.S. patent applications has resulted in the issuance of 27 U.S. patents, with four continuation applications still pending; the most recent continuation in this chain of applications was filed on June 10, 2013. Masimo may have filed even more continuation applications, which have not yet published. Masimo and its patent counsel have filed similarly endless chains of continuation and continuation-in-part applications for many of the above applications.

- 88. By comparison, as of the date of this pleading, Masimo holds only about 40 patents granted by the European Patent Office, the next most common venue in which patent protection is sought outside of the United States. This difference between Masimo's U.S. patent portfolio and what has been granted by the European Patent Office is directly related to the lack of continuation practice in Europe, which prevents the abusive patent filing strategy adopted by Masimo in the United States.
- 89. Prosecution laches is the practice of filing continuation applications long after the initial filing date of a patent application with the intent of writing claims in those continuation applications based on an invention not actually disclosed in the patent application, but instead to

read on products independently developed by others long after the patent applications were filed. Consequently, patents issue decades after the original patent issues or publishes, with claims broader than and/or unsupported in the application. *See, e.g., Symbol Technologies, Inc. et al. v. Lemelson Medical, Education & Research Foundation, L.P.*, 277 F.3d. 1361 (Fed. Cir. 2002) (citing *Woodbridge v. United States*, 263 U.S. 50 (1923) (nine year delay in seeking issuance of patent rendered patent unenforceable). The equitable doctrine of prosecution laches acts as a statute of repose, so that the public can reasonably rely on the coverage of a patent after it has issued. Masimo's practice of seeking broader patents decades after its initial patent has issued violates the public trust, frustrates the statutory scheme, and renders such patents unenforceable under the doctrine of prosecution laches.

- 90. Six of the Masimo patents asserted in the California litigation were filed more than nine years after the initially claimed priority application. The continuation application that matured as the '958 patent was filed on May 3, 2006, almost nine (9) years after its earliest claimed priority date of April 14, 1997. The continuation application that matured as the '154 patent was filed on August 20, 2007, almost thirteen (13) years after its earliest claimed priority date of October 7, 1994. The continuation application that matured as the '533 patent was filed on January 25, 2012, more than sixteen (16) years after its earliest claimed priority date of October 16, 1995. The continuation application that matured as the '986 patent was filed on June 15, 2005, more than ten (10) years after its earliest claimed priority date of October 7, 1994. The continuation application that matured as the '060 patent was filed on December 3, 2001, more than ten (10) years after its earliest claimed priority date of March 7, 1991. All of these patents are unenforceable under the doctrine of prosecution laches.
- 91. In addition to its abusive number of long-delayed filings, Masimo further abuses U.S. continuation practice by improperly dropping priority claims to extend the term of patents issued on its continuation applications. This is how Masimo, in the chain of patent applications recited above, apparently justifies filing a continuation patent application on June 10, 2013, even though the earliest application in the priority chain was filed on March 7, 1991 more than 20

years after the originally claimed priority date for the patent specification. Because the term of a U.S. patent filed on or after June 7, 1995 is only 20 years from its earliest claimed priority date, any patent to issue on Masimo's June 10, 2013 continuation application nominally should expire on March 7, 2011, i.e., before it can even issue. By filing its continuation applications with an early priority date, Masimo misleads the Patent Examiner to disregard the prior art dated after the claimed priority date. Masimo then selectively withdraws its priority claims, thereby lengthening the term of any patent issued on the application beyond 20 years.

- 92. Masimo's goal was to illegally create a dominant position for itself in the market for pulse oximeter monitors in the United States, that extends equally into the corresponding submarkets for standalone pulse oximeter monitors, MPPM monitors, OEM circuit boards, and the markets for pulse oximeter sensors and patient cables, by procuring an extensive portfolio of invalid and/or unenforceable patents; by improperly patenting inventions known to have been created by others; by deliberately pursuing patent claims known to lack support under one or more sections of 35 U.S.C. § 112, first paragraph; and/or by withholding material prior art from the USPTO during prosecution of Masimo's patents.
- 93. Mr. Kiani, Mr. Diab and Masimo's patent counsel, Knobbe Martens Olsen and Bear LLP ("the Knobbe Martens firm") have financially profited from this conduct, while innovation and competition in the markets for pulse oximeter circuit boards, MPPMs and accessories have been stifled, to the great loss and expense of the American public.
- 94. Upon information and belief, Mr. Kiani founded his company on technology hijacked from a prior employer, Newport Medical Electronics, Inc. ("Newport Medical") and key patents obtained by Masimo since then have claimed inventions that were first invented by Masimo's competitors, including at least Nellcor Incorporated ("Nellcor") and/or Philips Electronics ("Philips").
- 95. Upon information and belief, Mr. Kiani was hired in 1989 by Dr. Saum Nour of Newport Medical, a small California-based start-up company, to help Newport Medical develop a low cost pulse oximeter monitor. In the course of his work for Newport Medical, Mr. Kiani

proposed using an adaptive filter, and specifically, an adaptive noise canceller to remove noise in the red and infrared signals generated by the pulse oximeter sensor due to motion noise.

Newport Medical provided Mr. Kiani with the parts and financial resources to develop a breadboard circuit implementing his noise canceller concept.

- 96. Upon information and belief, Mr. Kiani thereafter resigned from Newport Medical, and sued Newport Medical to obtain ownership of the adaptive noise canceller concept he had developed while employed by that Company. Upon information and belief, Mr. Kiani executed a settlement agreement with Newport Medical by which Mr. Kiani agreed not to pursue meritless claims against Newport Medical in exchange for ownership of the technology he had developed for Newport Medical. In that settlement agreement, Mr. Kiani warranted that he had returned the breadboard circuit and computer coding that he had prepared while working for Newport Medical. Upon information and belief, Mr. Kiani did not return those items, but instead kept them as the basis for founding of Vital Signals Incorporated, which later became Masimo.
- 97. Promptly after defrauding Newport Medical of title to the pulse oximetry invention that he had made for it, Mr. Kiani in 1989 founded Vital Signals Incorporated to develop for his own financial gain a pulse oximeter board implementing the adaptive noise canceller technology. Mr. Kiani soon hired Mohamed Diab to assist in developing the adaptive noise canceller implementation of a pulse oximeter monitor, and by March of 1991, Masimo filed its first patent application directed to pulse oximeter monitors, U.S. patent application Serial No. 07/666,060 ("the '060 application") using counsel at the Knobbe Martens firm. That application embodied the adaptive noise canceller filtering technique that Mr. Kiani had taken from Newport Medical.

#### B. Commission of Inequitable Conduct in Related Masimo Patents

98. In or about 1999, Mr. Kiani, as Masimo's CEO, and Mr. Jensen, as litigation counsel for Masimo, sued Nellcor for infringement of U.S. Patent No. 6,036,642 ("the '642 patent") ("Masimo I"). That patent is a continuation application of the '060 application first filed on March 7, 1991, and as confirmed by the Federal Circuit, discloses adaptive noise cancellers as

the sole adaptive filtering technology for removing motion artifact from pulse oximeter monitor readings.

- 99. In response to Masimo's infringement claims in Masimo I, Nellcor moved for summary judgment of non-infringement. In connection with that motion, Nellcor submitted sealed declarations of Dr. Thomas Yorkey and Mr. Clark Baker ("the Yorkey and Baker Declarations"), which described in detail the algorithms used in Nellcor's N-395 pulse oximeter monitor. The Yorkey and Baker Declarations included as appendices many of the Nellcor internal reports describing Nellcor's independent development of those algorithms, demonstrating that Mr. Yorkey was in possession of the invention of using estimation techniques to compute blood oxygen saturation at least prior to December 1992. Masimo in *Masimo Corp. v. Mallinckrodt Inc.*, Dkt. No. 8:99-cv-01245 (C.D. Cal. Oct 08, 1999) ("Masimo I") accused Nellcor's N395 pulse oximeter monitor of infringing the '642 patent.
- 100. Nellcor prevailed in the Masimo I litigation, with the District Court issuing an Order filed October 4, 2000, granting summary judgment that the term "adaptive filter" used in the claims of that patent was synonymous with "adaptive noise canceller." The District Court in Masimo I found that Nellcor's commercial pulse oximeter monitors, which are described in the Yorkey and Baker Declarations as using a Kalman filter, did not use adaptive noise cancellers, the only type of adaptive filter disclosed in the '642 patent.
- 101. Masimo I conclusively established that Kalman filters were not adaptive filters, and were not disclosed in the '060 application first filed on March 7, 1991. Moreover, vis-à-vis the '060 application, Masimo I established that Nellcor had invented the use of Kalman filters before Masimo, and that Masimo could not rely on the March 7, 1991 filing date of the '060 application as proof of prior invention of Kalman filters, because no such filter is disclosed in the '060 application. That decision of the District Court was affirmed on appeal by the Federal Circuit in a decision reported at 18 Fed. Appx. 852 (Fed. Cir. 2001).
- 102. Subsequent to the Court's ruling in Masimo I, Masimo promptly filed another patent infringement case against Nellcor, *Masimo Corp. v. Mallinckrodt Inc.*, Dkt. No. 8:01-cv-

- 00638 (C.D. Cal. Jul. 09, 2001) ("Masimo II"), this time asserting a number of patents, including U.S. Patent No. 6,206,830 ("the '830 patent"). The '830 patent issued on March 27, 2001, as a continuation of the '642 patent, and contains an identical disclosure to the '060 application filed March 7, 1991.
- 103. Like the claims of the '642 patent, many claims of the '830 patent require an "adaptive filter" or "adaptive filtering." However, during prosecution of the '830 patent, Mr. Kiani and Mr. Jensen argued before the USPTO that the term "adaptive filter" as used in the claims should be broadly construed to read on any type of adaptive filter, not just the adaptive noise canceler disclosed in the application. Masimo did not submit to the Patent Examiner the District Court's decision in Masimo I that found that the disclosure of the '642 patent which was identical to the disclosure of the application for the '830 patent pending before the Patent Examiner did not contain support for any "adaptive filter" other than "adaptive noise canceller." In connection with post-trial proceedings in Masimo II, the District Court held the '830 patent unenforceable because the inventors and Mr. Jensen had withheld the District Court's opinion in Masimo I from the USPTO.
- affirming the District Court's determination that the '830 patent was unenforceable: "The district court correctly recognized that the Masimo I litigation directly affected the patentability of the invention claimed in the '830 patent because the same terms were at issue in both proceedings." *Mallinckrodt, Inc. v. Masimo Corp.*, 147 Fed. Appx. 158, 183 (Fed. Cir. 2005).
- 105. The Federal Circuit also held that there was clear evidence of intent to deceive the USPTO: "... the district court inferred intent from the actions of Jensen, Masimo's attorney. Any competent attorney registered to practice before the PTO should have known that the Masimo I litigation was material to the patentability of the invention claimed in the '830 patent. After all, a registered attorney is required to be familiar with the laws, regulations, and ethical standards implicated in practicing before the PTO. Hence, that Jensen did not disclose the Masimo I litigation to the PTO, when he for certain knew about it since he was the lead attorney

representing Masimo in that litigation, strongly suggests that he intended to deceive the PTO." *Id.* at 183-84.

- 106. There, as here, Masimo and its patent counsel were engaged in prosecuting patents intended to cover the target of pending litigation, after having received highly proprietary and confidential information regarding the algorithms used in Nellcor's N395 pulse oximeter monitor, which Masimo had unsuccessfully accused of infringement in Masimo I.
- 107. The Yorkey and Baker declarations submitted in Masimo I originally had been filed under seal. Upon information and belief, Masimo's patent prosecution and litigation counsel in Masimo I and II, studied those materials to formulate additional claims that Masimo and the Knobbe Martens firm then prosecuted in subsequent patent applications, including the unenforceable '830 patent. That these declarations had been considered by Masimo's patent prosecutors at the Knobbe Martens firm is evident from Masimo's selective submission of these declarations in certain of the patents asserted in the California litigation, as described *infra*.
- 108. The District Court's decision in Masimo II could not lead to a contrary conclusion that the '060 application supported Masimo's claims to have invented Kalman filtering techniques for removing motion noise from pulse oximeter measurements before Nellcor. That is because Masimo I, which should have been law of the case, established that the '060 application did not disclose anything other than adaptive noise cancelers, and Kalman filters were not adaptive noise cancelers. Moreover, if Masimo II, as affirmed by the Federal Circuit, had concluded that the '060 application established a reduction to practice by Masimo of Kalman filters, then the Federal Circuit would not have found the related '830 patent unenforceable because in that case the '060 application would have supported an interpretation of "adaptive filter" broader than just adaptive noise cancelers.

# C. Unenforceability of the '958 PatentDeliberate Withholding of the Yorkey and Baker Declarations

109. The application for the '958 patent was filed on May 3, 2006, and claims priority through a chain of patent applications first filed on April 14, 1997; the '958 patent issued on

February 10, 2009. Apart from being unenforceable for prosecution laches as described above, the '958 patent further is unenforceable because Masimo and its counsel committed inequitable conduct during prosecution of the application by withholding certain exhibits to the Yorkey and Baker Declarations in Masimo I, and the trial testimony and exhibits of Dr. Robert T. Stone from the Masimo II trial, as set forth in detail *infra*.

- 110. Issued claim 1 of the '958 patent recites: In a signal processor, a method of determining measurements for one or more blood parameters of pulsing blood, the method comprising: (a) receiving a first intensity signal from a light-sensitive detector which detects light of a first wavelength attenuated by body tissue carrying pulsing blood; (b) receiving a second intensity signal from the light-sensitive detector which detects light of a second wavelength attenuated by body tissue carrying pulsing blood; (c) electronically transforming the first and second intensity signals into the frequency domain; (d) electronically determining values of the transformed first and second intensity signals that represent desired physiological data; (e) electronically combining the transformed first and second intensity signals to form a composite signal comprising physiological information from both the transformed first and second intensity signals; (f) electronically analyzing the composite signal using one or more physiologically-based rules; and (g) electronically determining the measurement of the blood parameter based at least in part on results of the analysis. (Reference letters added.)
- 111. The prosecution history of the '958 patent reveals that the Patent Examiner, Examiner Winakur, rejected application claims 1, 2, and 4 as anticipated by Mortz, U.S. Patent No. 5,934,277, under 35 U.S.C. § 102(e). *See* Non-Final Rejection dated January 3, 2008, pp. 3-4. The Examiner also rejected pending claim 3 as obvious over Mortz under 103(a). *See id*.
- 112. Examiner Winakur further identified Corenman, Nellcor's U.S. Patent No. 4,911,167 ("Corenman"), as prior art. *See* Amendment dated July 1, 2008, pp. 11-12. Corenman discloses "a method and apparatus for improving *the calculation of oxygen saturation and other blood constituents*....The processing may occur in the time domain or in the *frequency domain*....In the preferred frequency domain embodiment, the time-measure [input signals] are

Fourier transformed into its spectral components to form the composite information." See Corenman, Abstract. The method disclosed in Corenman includes a photodetector that generates a current in response to the *red and infrared light* transmitted in sequence and is converted to a voltage signal. See Corenman, col. 2, 11. 3-5.

- 113. Responding to the Examiner's rejections, applicants amended application claim 1 to additionally recite "transforming the first and second intensity signals into the frequency domain," "combining the transformed first and second intensity signals to form a composite signal comprising physiological information from both the transformed first and second intensity signals;" "analyzing the composite signal using one or more *physiologically-based rules*;" and "determining the measurement of the blood parameter based at least in part on the results of the analysis." *See* Amendment dated July 1, 2008, p. 2.
- 114. Applicants further amended application claim 1 to recite that the method of transforming, combining, determining, and analyzing the signals be performed *electronically* in a *signal processor*. *See* Amendment dated October 15, 2008, p. 2. In distinguishing the claims of the '958 patent over Corenman, Masimo and its lawyers specifically argued that the Corenman patent did not disclose "analyzing [a] composite signal using one or more physiologically-based rules." *See* Amendment filed July 1, 2007 at pages 11-12. The Examiner allowed pending claim 1 after entering the above amendments. *See* Notice of Allowance dated November 5, 2008. Thus, the preceding amendments were viewed by the Patent Examiner as patentably distinguishing features of the '958 patent over the cited prior art.
- 115. Corenman discloses a method of computing a blood parameter, in particular blood oxygen saturation, using red and infrared data transformed from the time domain to the frequency domain using a Fourier Transform. *See, e.g.*, Corenman FIG. 10, which discloses practicing in a pulse oximeter each of the following limitations of claim 1 of the '958 patent:
  - (a) receiving a first intensity signal from a light-sensitive detector which detects light of a first wavelength attenuated by body tissue carrying pulsing blood (*See* Corenman FIG. 10, step 4000 "collect 512 data points on each of the Red and IR data");

- (b) receiving a second intensity signal from the light-sensitive detector which detects light of a second wavelength attenuated by body tissue carrying pulsing blood (*See* Corenman FIG. 10, step 4000 "collect 512 data points on each of the Red and IR data"); (c) electronically transforming the first and second intensity signals into the frequency domain (*See* Corenman FIG. 10, step 4070 "Compute F.T. [Fourier Transform] of Red and IR data");
- (d) electronically determining values of the transformed first and second intensity signals that represent desired physiological data (*See* Corenman FIG. 10, step 4080 "Locate peaks at Heart Rate" ["desired data"]);
- (e) electronically combining the transformed first and second intensity signals to form a composite signal comprising physiological information from both the transformed first and second intensity signals (*See* Corenman FIG. 10, step 4080 "Compute R" [the "ratio of ratios" which is determined by combining the transformed Red and Infrared signals to compute a composite signal of the two transformed signals]); and
- (f) electronically analyzing the composite signal using one or more physiologically-based rules (*see infra*); and
- (g) electronically determining the measurement of the blood parameter based at least in part on results of the analysis (*See* Corenman FIG. 10, final step "Compute SAT (Usual Nellcor Form)" [in which R value of the "ratio of ratios" is used to look up or compute a value of blood oxygen saturation]).
- 116. The only limitation of claim 1 that is missing from Corenman is the limitation (f) of claim 1 of the '958 patent using one or more physiologically-based rules to analyze the composite signal. That feature, however, is fully disclosed in the Nellcor internal documents appended to the Yorkey and Baker Declarations that Mr. Kiani, Mr. Diab and Masimo's counsel deliberately withheld from the Patent Office during prosecution of the '958 patent.
- 117. The Yorkey and Baker Declarations, which were executed in August 2000, had attached thereto Nellcor internal reports created between 1992 and 1994. The Nellcor internal

reports predate the 1997 filing date of the '958 patent by several years, and constitute prior art to the '958 patent under at least 35 U.S.C. 102(g). The Yorkey and Baker Declarations and exhibits, and particularly the Nellcor internal reports, are highly material to the patentability of the '958 patent, because they were both well known to Mr. Kiani and Mr. Diab, and attorneys at Knobbe Martens, including Mr. Jensen and Mr. Grover, and because they disclose the key limitation of the '958 patent that was added to secure allowance of that patent. Masimo published the Yorkey and Baker Declarations and exhibits in connection with issuance of Masimo's U.S. Patent No. 7,469,157, which names Mr. Kiani, Mr. Diab and Mr. Weber as coinventors.

- disclose details of Nellcor's O4 pulse oximeter project, begun in 1992, to develop software algorithms that provided valid measurements in the present of motion noise. As described, e.g., Exhibit 2 to the Yorkey Declaration, that system was designed to process values for the red and infrared signals received from the oximeter sensor to reduce the impact of motion or other noise on the overall average computed value of blood oxygen saturation. *See* O4 Summary dated August 5, 1994, Exhibit 2 to the Yorkey Declaration at page at 1 ("In the fall of 1992, the O4 project began researching oximetry algorithms with the goals of substantially reducing false alarms compared to the N200, and calculating saturation and rate *through periods of motion*.")(emphasis added).
- 119. As further described at page 3 of Exhibit 2 to the Yorkey Declaration, a Nellcor document dated August 5, 1994 and entitled "O4 Summary": "O4 calculates two saturations, one with the data that has been comb filtered with the current estimate of the heart rate, the other is the raw preprocessed data. *O4 calculates saturation with an adaptive (Kalman) filter that continuously weighs all data by an estimate of the current noise and limits the rate of change to a defined limit (currently 1.3 saturation points per second). Data points which are obviously non-physiological, such as when IR and red values are moving in opposite directions, are deemed invalid and not used to adapt saturation" (emphasis added). The*

foregoing passage of Exhibit 2 to the Yorkey Declaration plainly discloses limitation (f) of claim 1 of the '958 patent of analyzing a composite signal using one or more physiologically-based rules. But for Masimo's and its counsel's failure to cite the Yorkey and Baker Declarations and exhibits to the USPTO, the '958 patent would not have issued.

- 120. As established above, Exhibit 2 to the Yorkey Declaration, in combination with the Corenman patent cited by the Patent Examiner, meets *all* of the limitations of claim 1 of the '958 patent, thus rendering claim 1 *prima facie* invalid. The '958 patent would not have issued had Mr. Diab, the inventor, or Messrs. Jensen and Grover, the patent counsel, cited the Yorkey and Baker materials to the Patent Examiner for review. Had the Examiner known about this prior art Nellcor work as described in Exhibit 2 to the Yorkey Declaration, at least claim 1 of the '958 patent would not have issued.
- Examiner during prosecution of the '958 patent. Given that Exhibit 2 to the Yorkey Declaration precedes the 1997 filing date for the application for the '958 patent by several years, Masimo could not have filed a declaration "swearing behind" the Nellcor documents had they been submitted by Masimo and cited by the Patent Examiner as prior art under 35 U.S.C. § 102(g). Mr. Jensen participated in and/or supervised prosecution of the '958 patent, as is evident from his participation with Mr. John Grover, Esq., also from the Knobbe Martens firm, at an Examiner Interview conducted on June 14, 2008, as disclosed in the prosecution history of the '958 patent. *See* Amendment dated July 1, 2008, p. 10.
- 122. The Yorkey and Baker Declarations and exhibits are non-cumulative to the other prior art made of record during prosecution of the '958 patent because the Examiner did not identify or cite any other prior art reference that disclosed analyzing a composite signal using physiological-based rules to determine a blood parameter.
- 123. Masimo and its counsel knew about the contents of the Yorkey and Baker Declarations and exhibits since at least August 2000; Mr. Jensen was lead counsel for Masimo in the Masimo I case. And by 2005, Masimo and its counsel had published the Yorkey and Baker

Declarations and exhibits in connection with prosecution of Masimo's U.S. Patent No. 7,469,157. Yet Masimo's inventors and its patent counsel deliberately choose to withhold those highly material references from the Patent Examiner to prevent having that prior art cited against the '958 patent.

- patent exposed, Masimo and its litigation counsel in the California litigation (which also participated in procuring the '958 patent), now contend that the Yorkey and Baker Declarations were brought to the Patent Examiner's attention. Specifically, Masimo and its counsel now contend that in July 2008, more than two years after the patent application for the '958 patent had been filed, and more than six months after the Examiner had issued the first rejection, Masimo's counsel submitted a transmittal letter to the Patent Examiner informing the Examiner that Masimo had submitted prior art in the files for 27 other Masimo issued patents and pending patent applications. *See* Transmittal Letter dated July 23, 2008. That transmittal letter did not identify the Yorkey and Baker Declarations, or even disclose in which of the other 27 files for the pending applications or issued patents relevant prior art could be found. Masimo also did not provide the Information Disclosure Statements ("IDS's") filed in those 27 other patents and applications.
- 125. Even if Masimo had submitted the IDS's filed in those other applications (prior to issuance of the '958 patent in 2009), which Masimo did not, those IDS's total more than 550 pages and collectively identify more than 5200 references, including patents, publications and trial transcripts. Assuming even a relatively short nominal patent length of 20 pages per patent, those 5200 references would correspond to more than 100,000 pages, or more than 40 completely full archive boxes of material.
- 126. During prosecution of the '958 patent, Masimo and its counsel submitted about 200 prior art references, which are actually listed on the IDS's filed for the '958 patent. Examiner Winakur indicated in the file history that he reviewed all 191 references in a single day on December 21, 2007. *See* List of References Cited by Applicant and Considered by Examiner,

dated September 25, 2008. Again, assuming a nominal patent length of only 20 pages per reference, Examiner Winakur purportedly read about 4000 pages of prior art on December 21, 2007. To have reviewed 4000 pages of prior art in an 8-hour work day, assuming no interruption, Examiner Winakur could not have spent more than about 7 seconds, on average, on each page of prior art. There is no indication in the file history for the '958 patent that he ever considered any of the prior art cited in the 27 other patents and applications mentioned in Masimo's transmittal letter, nor given the foregoing schedule, did he have time to do so.

- 127. In view of the circumstances, the single most reasonable inference regarding the '958 patent is that Masimo's inventors and Messrs. Jensen and Grover mentioned the 27 other patent and application files, fully expecting that Examiner Winakur could not review that mountain of prior art, and indeed purposely intended to discourage and prevent Examiner Winakur from reviewing any of the prior art contained in those other patent and application files. This inference is bolstered by the statement in Masimo's Transmittal Letter that the '958 application did "not claim a priority benefit to any of these patents or pending applications" and thus were directed to different subject matter. *See* Transmittal Letter dated July 23, 2008.
- 128. Masimo's inventors and its counsel had a duty to cross-cite all material information irrespective whether the same examiner previously receiving the information is responsible for the patent application at issue, but they deliberately chose not to do so to secure allowance of the '958 patent. Examiner Winakur has examined and issued at least 173 patents to Masimo; he could not possibly be expected to recall that any particular reference amongst the thousands of references Masimo cited in those other applications might apply to the '958 patent years later.
- 129. As set forth above, the Nellcor internal documents attached to the Yorkey and Baker Declarations, and in particular Exhibit 2 to the Yorkey Declaration, was highly material to patentability of at least claim 1 of the '958 patent. Exhibit 2 to the Yorkey Declaration described exactly the type of application of physiological rules to a composite red and infrared signal that Masimo's inventors and its counsel argued was absent from the Corenman reference; but for

withholding that material, claim 1 of the '958 patent would not have issued. The content of the Yorkey and Baker Declarations was well known to Masimo's inventors and patent/litigation counsel, and they had in fact cited these materials in many other Masimo applications. Had Masimo or its counsel cited the Yorkey and Baker Declarations and exhibits to the Patent Examiner examining the application for the '958 patent, however, they knew that they could not swear behind the dates of the Nellcor internal reports, in the event the Patent Examiner cited the Nellcor work as prior art. Under the circumstances, the single most likely inference regarding Masimo's and its counsel's failure to cite the Yorkey and Baker Declarations and exhibits is that Masimo and its counsel deliberately withheld that information from consideration by the Patent Examiner during prosecution of the '958 patent.

### **Deliberate Withholding of the Masimo II trial materials**

- 130. Additionally, Masimo and its counsel committed inequitable conduct in connection with prosecution of the '958 patent, not only for failing to cite the Yorkey and Baker Declarations and exhibits, but also by failing to submit to the USPTO the trial testimony of Dr. Robert T. Stone presented during the Masimo II trial. Mr. Kiani attended the Masimo II trial, and Mr. Jensen was both litigation counsel in Masimo II and directly participated and/or supervised prosecution of the '958 patent.
- 131. Dr. Stone's trial testimony and exhibits disclose a prototype fetal oximeter and methods developed by Nellcor in the late 1980s, which system also constitutes highly material prior art to the claims of the '958 patent, including claim 1, under 35 U.S.C. § 102(g). But for Masimo's and its counsel's deliberate withholding of the fetal oximeter described in Dr. Stone's trial testimony and exhibits, at least claim 1 of the '958 patent would not have issued.
- 132. As discussed *supra*, during prosecution of the '958 patent, Examiner Winakur identified Corenman, Nellcor's U.S. Patent No. 4,911,167 ("Corenman"), as prior art. *See*Amendment dated July 1, 2008, pp. 11-12. Corenman discloses "a method and apparatus for improving *the calculation of oxygen saturation and other blood constituents*....The processing may occur in the time domain or in the *frequency domain*...In the preferred frequency domain

embodiment, the input signals are *Fourier transformed* into its spectral components to form *the composite information*." *See* Corenman, Abstract. The method disclosed in Corenman includes a photodetector that generates a current in response to the *red and infrared light* transmitted in sequence and is converted to a voltage signal. *See* Corenman, col. 2, 11. 3-5.

- of the '958 patent to additionally recite "transforming the first and second intensity signals into the frequency domain," "combining the transformed first and second intensity signals to form a composite signal comprising physiological information from both the transformed first and second intensity signals;" "analyzing the composite signal using one or more *physiologically-based rules*;" and "determining the measurement of the blood parameter based at least in part on the results of the analysis." *See* Amendment dated July 1, 2008, p. 2.
- 134. Applicants further amended application claim 1 to recite that the method of transforming, combining, determining, and analyzing the signals to be performed *electronically* in a *signal processor*. *See* Amendment dated October 15, 2008, p. 2. In distinguishing the claims of the '958 patent over Corenman, Masimo and its lawyers specifically argued that Corenman did not disclose "analyzing [a] composite signal using one or more physiologically-based rules." *See* Amendment filed July 1, 2007 at pages 11-12. The Examiner allowed pending claim 1 after entering the above amendments. *See* Notice of Allowance dated November 5, 2008. Thus, the preceding amendments were viewed by the Patent Examiner as patentably distinguishing features of the '958 patent over the cited prior art.
- 135. Corenman discloses a method of computing a blood parameter, in particular blood oxygen saturation, using red and infrared data transformed from the time domain to the frequency domain using a Fourier Transform. *See, e.g.*, Corenman FIG. 10, which discloses practicing in a pulse oximeter each of the following limitations of claim 1 of the '958 patent:
  - (a) receiving a first intensity signal from a light-sensitive detector which detects light of a first wavelength attenuated by body tissue carrying pulsing blood (*See* Corenman FIG. 10, step 4000 "collect 512 data points on each of the Red and IR data");

- (b) receiving a second intensity signal from the light-sensitive detector which detects light of a second wavelength attenuated by body tissue carrying pulsing blood (*See* Corenman FIG. 10, step 4000 "collect 512 data points on each of the Red and IR data"); (c) electronically transforming the first and second intensity signals into the frequency domain (*See* Corenman FIG. 10, step 4070 "Compute F.T. [Fourier Transform] of Red and IR data");
- (d) electronically determining values of the transformed first and second intensity signals that represent desired physiological data (*See* Corenman FIG. 10, step 4080 "Locate peaks at Heart Rate" ["desired data"]);
- (e) electronically combining the transformed first and second intensity signals to form a composite signal comprising physiological information from both the transformed first and second intensity signals (*See* Corenman FIG. 10, step 4080 "Compute R" [the "ratio of ratios" which is determined by combining the transformed Red and Infrared signals to compute a composite signal of the two transformed signals]); and
- (f) electronically analyzing the composite signal using one or more physiologically-based rules (*see infra*); and
- (g) electronically determining the measurement of the blood parameter based at least in part on results of the analysis (*See* Corenman FIG. 10, final step "Compute SAT (Usual Nellcor Form)" [in which R value of the "ratio of ratios" is used to look up or compute a value of blood oxygen saturation]).
- 136. The only limitation of claim 1 that is missing from Corenman is limitation (f) of claim 1 of the '958 patent using one or more physiologically-based rules to analyze the composite signal. That feature and more, however, is disclosed in Dr. Stone's trial testimony at Masimo II regarding Nellcor's fetal oximeter system, which Mr. Kiani, Mr. Diab and Masimo's counsel deliberately withheld from the Patent Office during prosecution of the '958 patent.
- 137. Dr. Stone's testimony and the trial exhibits disclose that Nellcor's fetal oximeter computed blood oxygen saturation via two alternative methods: a first method that used

conventional time-based algorithms to compute saturation, and a second frequency domain method in which the red and infrared signals were transformed into the frequency domain and then used to form a composite signal, which in turn was used to compute oxygen saturation. The Nellcor fetal oximeter output two values of oxygen saturation, from which a correct result was selected based on physiologically-based rules. *See* Stone Masimo II testimony, pp. 1819-1820 and Slide 4905.

- testimony shows Red and IR arrows directed to boxes labeled N-200 Signal Processing and Frequency-Domain Signal Process Techniques, thus meeting limitations (a) and (b) of claim 1 of the '958 patent. The Frequency Domain Processing meets limitation (c), (d) and (e) of claim 1 of the '958 patent. See id. at 1820-1821 and Slide 4905. Dr. Stone further testified that the fetal oximeter arbitrates among the values computed by different approaches by selecting the "best result" from those displayed in the fetal oximetry program, and the selection is based on the characteristics of the physiological signal. See id. at 1821. This feature of the Nellcor fetal oximeter satisfies limitations (f) and (g) of claim 1 of the '958 patent. Accordingly, but for the failure by Masimo's inventors and its patent counsel to disclose Dr. Stone's trial testimony and exhibits at the Masimo II trial, at least claim 1 of the '958 patent would not have issued.
- 139. In addition to anticipating at least claim 1 of the '958 patent, the Nellcor fetal oximeter disclosed in Dr. Stone's testimony supplied that which was missing from Corenman, and in combination with Corenman renders at least claim 1 of the '958 patent invalid as obvious. Dr. Stone's trial testimony and trial exhibits are non-cumulative to the prior art cited to and considered by Examiner Winakur during prosecution of the '958 patent because they describe each and every limitation of claim 1, including the purportedly inventive limitation.
- 140. Mr. Kiani and Mr. Diab, who upon information and belief attended the Masimo II trial, and Mr. Jensen, who was both litigation counsel at the Masimo II trial and participated in prosecuting the '958 patent, were aware of Dr. Stone's trial testimony and exhibits. Masimo and

its counsel did not provide Dr. Stone's Masimo II trial testimony or exhibits to the Patent Examiner during prosecution of the '958 patent.

- 141. Masimo contends that it brought Dr. Stone's testimony at the Masimo II trial to the Patent Examiner's attention during prosecution of the '958 patent by listing the application file, Appl. No. 11/154093, that matured as the '986 patent along with 27 other patent and application files mentioned in a transmittal letter accompanying an IDS filed for the '958 patent. *See* Transmittal Letter dated July 23, 2008. However, that application file does not appear amongst the items actually listed on Masimo's IDS, and Masimo has no reason to believe that the Patent Examiner ever looked beyond the prior art actually submitted during prosecution of the '958 patent. There is no indication in the file history of the '958 patent that the Stone trial testimony from Masimo II was ever considered in connection with examination of the '958 patent. Moreover, the exhibits that accompanied Dr. Stone's Masimo II trial testimony were not even submitted during prosecution of the '986 patent, ensuring that Dr. Stone's Masimo II trial testimony was not even considered during prosecution of that patent.
- 142. As for the Yorkey and Baker Declarations and exhibits, the Nellcor fetal oximeter described in Dr. Stone's Masimo II trial testimony predates the filing date of the '958 patent by many years, and constitutes prior art under 35 U.S.C. § 102(g). Accordingly, Masimo could not have overcome a rejection by the Patent Examiner citing the Nellcor fetal oximeter, and Masimo could not have filed a declaration "swearing behind" that prior art.
- 143. Mr. Kiani, Mr. Diab and Masimo's patent counsel deliberately and intentionally withheld Dr. Stone's Masimo II trial testimony and exhibits regarding Nellcor's fetal oximeter so that it could not be cited by the Patent Examiner as rendering unpatentable the claims that Masimo sought to obtain in the '958 patent. In view of the foregoing, the single most reasonable inference is that Masimo and its patent counsel deliberately withheld Dr. Stone's Masimo II trial testimony and exhibits to induce the Patent Examiner to allow the claims of the '958 patent. Accordingly, all claims of the '958 patent are unenforceable due to inequitable conduct.

- 144. As alleged above, Masimo committed inequitable conduct during prosecution of the '958 patent by failing to disclose to the USPTO the Yorkey and Baker materials and by failing to submit to the USPTO Dr. Stone's trial testimony presented during the Masimo II trial, each of which information is both highly material to patentability of the claims of the '958 patent and would have precluded issuance of at least claim 1 of the '958 patent.
- 145. The foregoing allegations regarding commission of inequitable conduct regarding the prosecution of the '958 patent are summarized in the following allegations:
- 146. <u>WHO</u>: As alleged above, but for Mr. Kiani's, Mr. Diab's, Mr. Jensen's and Mr. Grover's decision to deliberately and intentionally withhold during prosecution of the '958 patent (1) the Yorkey and Baker Declarations and exhibits and (2) Dr. Stone's Masimo II trial testimony and exhibits, the claims of the '958 patent would not have issued.
- Baker Declarations and exhibits, and in particular Exhibit 2 to the Yorkey Declaration, which discloses at page 3 the use of physiologically based rules to analyze a composite signal based on red and infrared signals. This was the only element missing from Corenman, which otherwise anticipated claim 1 of the '958 patent. And separately, as alleged above, Masimo and its counsel withheld Dr. Stone's Masimo II trial testimony and exhibits, which disclosed at pages 1819-1821 and in Slide 4905 a fetal oximeter that generated oxygen saturation values using two different algorithms, including a frequency-based analysis, and then arbitrated between those results using physiologically-based rules to determine a valid output. That testimony and exhibit anticipates at least claim 1 of the '958 patent, or alternatively renders claim 1 unpatentable in combination with Corenman.
- 148. <u>WHERE</u>: Page 3 of Yorkey Declaration Exhibit 2 describes in detail at least one physiologically based rule applied to the composite of the red and infrared signals. Pages 1819 to 1821 of the Masimo II trial transcript and Slide 4905 used in conjunction with that testimony describe the details of the Nellcor fetal oximeter. Nellcor technology having the features later

claimed by Masimo in the '958 patent was developed well before the 1997 filing date for the application that matured as the '958 patent.

- rules at page 3 of the withheld Exhibit 2 to the Yorkey Declaration, dated August 1994, supplies the sole claim limitation missing from Corenman. More specifically, Corenman disclosed all limitations of claim 1 of the '958 patent except the limitation requiring analyzing a composite signal formed by combining the red and infrared signals using physiologically-based rules. Exhibit 2 to the Yorkey Declaration provides that missing limitation, rendering claim 1 of the '958 patent unpatentable. Likewise, Dr. Stone's Masimo II trial testimony and exhibits describe a fetal oximeter developed by Nellcor during Dr. Stone's tenure, prior to 1989, that computed oxygen saturation using alternative calculation methods, one of which was a frequency-based analysis. If the results of these calculations differed, physiologically-based rules were applied to decide whether to select Saturation 1 resulting from the N-200 Signal Processing Branch or Saturation 2 resulting from the Frequency Domain analysis. Nellcor's prior art fetal oximeter therefore provides the sole missing element of at least claim 1 of the '958 patent that was not disclosed in Corenman.
- 150. HOW: But for the deliberate withholding of the Yorkey and Baker Declarations and exhibits, and separately, withholding of Dr. Stone's Masimo II trial testimony and exhibits, including Slide 4905, Examiner Winakur would have rejected at least claim 1 of the '958 patent, as obvious under 35 U.S.C. § 103 based on Corenman in view of Exhibit 2 to the Yorkey Declaration, under 35 U.S.C. § 102(g) as anticipated by Nellcor's fetal oximeter, or obvious over Nellcor's fetal oximeter in view of Corenman. Nellcor's prior art materials establish that it first invented limitation (f) that Examiner Winakur found to be absent in the other prior art of record. The Yorkey and Baker Declarations and exhibits and Dr. Stone's Masimo II trial testimony was not inadvertently omitted by Masimo and its counsel, but rather deliberately withheld to ensure that Examiner Winakur issued the '958 patent.

### D. Unenforceability of the '986 Patent

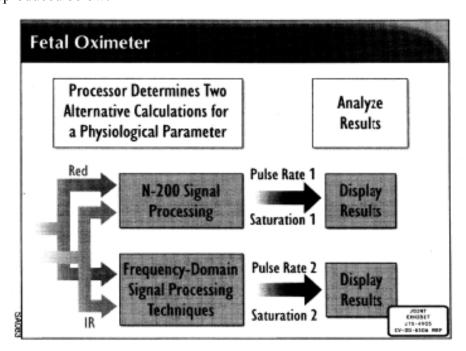
- 151. Mr. Kiani, Mr. Jensen and others at the Knobbe Martens firm who were involved in the Masimo I and II trials and prosecution of Masimo's patents committed inequitable conduct in connection with prosecuting the '986 patent, asserted in the California litigation, by failing to submit to the USPTO the trial exhibits needed to understand key portions of Dr. Stone's Masimo II trial testimony.
- 152. During prosecution of the '986 patent, Masimo submitted more than 4000 pages of trial transcript from Masimo II, but did not provide any guidance to the Patent Examiner where any testimony relevant to the claimed invention of the '986 patent could be found. Masimo also did not provide the Patent Examiner with the trial exhibits or demonstratives that accompanied that trial testimony, so even if the Patent Examiner had the time to review the Masimo II trial testimony, he would not have known where to look in the transcript. And even if the Examiner did locate the relevant portions of the transcript, he would not have understood it without at least Slide 4905, which forms an integral part of that testimony. Moreover, to the extent that the Masimo II trial testimony was provided at all, it was buried amongst more than 200 patents and 250 items of non-patent literature, representing tens of thousands of pages of material.
- Mr. Kiani and Mr. Jensen could have provided the relevant exhibits from the Masimo II trial so the Patent Examiner could get some sense of what was contained in the truckload of references that Masimo dropped on the Examiner's desk. But instead they deliberately withheld those trial exhibits, especially Slide 4905 used in conjunction with Dr. Stone's testimony at Masimo II, so that the Patent Examiner could not possibly consider Dr. Stone's trial testimony. Masimo and its patent counsel committed inequitable conduct in connection with prosecution of the '986 patent, and but for withholding of Slide 4905 and Masimo's burying Dr. Stone's Masimo II trial testimony in a mountain of less relevant material, at least claim 1 of the '986 patent would not have issued.
- 154. Claim 1 of the '986 patent, which issued in 2007, recites: A method of determining blood oxygen saturation comprising: (a) sensing physiological signals resulting from

the attenuation of light of at least first and second wavelengths by body tissue carrying pulsing blood; (b) determining at least two values corresponding to oxygen saturation based upon at least two alternative methods of using the physiological signals; and (c) determining a resulting value for oxygen saturation from the at least two values corresponding to oxygen saturation, (d) wherein one of the at least two alternative methods comprises at least one calculation in the frequency domain. (Reference letters added.)

- 155. On September 11, 2006, Masimo's patent counsel of record, Messrs. John Grover and Jarom Kesler, and the Patent Examiner, Mr. Winakur, conducted an in-person interview to reach an agreement on the claims then pending in the application for the '986 patent. As a result of that meeting, claim limitation (d) was amended to recite: wherein one of the at least two alternative methods comprises at least one calculation in the frequency domain. *See* Amendment dated September 13, 2006, p. 2. The amendment highlights that claim 1 of the '986 patent requires at least two alternative methods for determining oxygen saturation, and one of the methods must be a calculation in the frequency domain.
- 156. At the Masimo II trial, Dr. Robert Stone testified regarding Nellcor's fetal oximeter, which he developed while employed at Nellcor prior to 1989. Dr. Stone also referred to Slide 4905, which illustrated the arrangement of the processing components making up the fetal oximeter. Dr. Stone testified with respect to Slide 4905 that Nellcor's fetal oximeter determined two values corresponding to oxygen saturation based upon two alternative methods of using the sensor data, one in the time domain and the other calculation in the frequency domain. *See* Masimo II trial transcript at pages 1819-1821.
- 157. Mr. Kiani, who attended the Masimo II trial, and Mr. Jensen, who was both litigation counsel at the Masimo II trial and participated in prosecuting the '958 patent, were aware of Dr. Stone's trial testimony and exhibits. Masimo and its counsel provided the Masimo II trial transcripts to the Patent Examiner along with more than 400 other patent and non-patent references, totaling several tens of thousands of pages. Dr. Stone's testimony regarding the Nellcor fetal oximeter was buried deep within the Masimo II trial transcripts. To ensure that the

Patent Examiner could not possibly find the relevant testimony, Masimo and its patent counsel withheld Dr. Stone's trial exhibits, such as Slide 4905, which is necessary both *to locate* and *to understand* the relevance of Dr. Stone's trial testimony.

158. But for Masimo's and its counsel's failure to submit Dr. Stone's Masimo II trial exhibits to the Patent Examiner, the '986 patent would not have issued. This is evident from the fact that the Patent Examiner did not in fact find Dr. Stone's Masimo II trial testimony in the mountain of materials submitted by Masimo during prosecution of the '986 patent, although the fetal oximeter plainly anticipates at least claim 1 of the '986 patent, as explained infra. Slide 4905 is reproduced below:



- 159. Complete correspondence between Nellcor's fetal oximeter and claim 1 of the '986 patent, and thus anticipation of claim may be demonstrated as follows:
  - (a) sensing physiological signals resulting from the attenuation of light of at least first and second wavelengths by body tissue carrying pulsing blood (*See* Slide 4905, which shows Red and IR signals being input to the N-200 Signal Processing and Frequency-Domain Signal Process Techniques);

- (b) determining at least two values corresponding to oxygen saturation based upon at least two alternative methods of using the physiological signals (*See* Slide 4905, which shows Red and IR signals being input to the N-200 Signal Processing block, a time-based analysis technique, and separately into to the Frequency-Domain Signal Processing block); and
- (c) determining a resulting value for oxygen saturation from the at least two values corresponding to oxygen saturation (*See* Slide 4905, which shows a value of Saturation 1 being output from the N-200 Signal Processing block, and a value of Saturation 2 being output from the Frequency-Domain Signal Processing block),
- (d) wherein one of the at least two alternative methods comprises at least one calculation in the frequency domain (*See* Slide 4905, in which the Frequency-Domain Signal Processing Technique constitutes at least one calculation in the frequency domain).
- 160. Slide 4905 illustrates Dr. Stone's Masimo II trial testimony and explains in a simple and straightforward way how the components of the Nellcor fetal oximeter were arranged and interacted. By contrast, the trial testimony presented at pages 1817 to 1821 of the Masimo II transcript is disjointed and difficult to understand without the assistance of Slide 4905.
- 161. For example, Dr. Stone testified at page 1817 that the fetal oximeter "allowed us to investigate parallel different processing techniques." At page 1818 Dr. Stone testified that "I wrote the so-called frequency domain techniques and then combined that algorithm in a I euphemistically used the term portable computer ... [which] acquired the data from an N-200, and it acquired the signals, the red and the infrared signals from an N-200 and displayed the data that the N-200 calculated as well as the data that the frequency domain technique calculated for me to evaluate." The questions and Dr. Stone's succeeding testimony on pages 1819 through 1821 specifically refers to Slide 4905, including references to "the red and infrared signals coming in on the left" and what is displayed "over on the far right [of Slide 4905]." Without having Slide 4905 in his possession to understand Dr. Stone's trial testimony, the Patent Examiner could not possibly have understood Dr. Stone's testimony as set forth in the Masimo II

trial transcript. Moreover, without having Slide 4905 in his possession, the Examiner Winakur would never have even located the relevant portions of the Masimo II transcript to review in the first place.

- 162. During his direct testimony in Masimo II, in response to the question whether "this slide [Slide 4905] represent in a very high level format, some of the processing or alternative calculations that you designed into the fetal oximetry program back in the period between 1983 and 1989," Dr. Stone testified that the "slide is very clear." Had Slide 4905 been submitted during prosecution of the '986 patent, it would have aided the Patent Examiner to both locate and understand Dr. Stone's Masimo II trial testimony. Since Masimo and its counsel deliberately withheld Slide 4905 during prosecution of the '986 patent, it is self-evident that the Patent Examiner did not locate Dr. Stone's testimony buried amongst the other references, or if he did (and there is no evidence that he did), the Examiner did not understand because he allowed claim 1 of the '986 patent, which is *prima facie* anticipated by the Nellcor fetal oximeter.
- 163. Slide 4905 was not cumulative to the bare transcript of Dr. Stone's Masimo II trial testimony. As alleged above, Dr. Stone's pages 1817 to 1818 of the transcript do not state that the same red and infrared sensor signals are input to both of the N-200 and Frequency-Domain Processing Techniques, although that arrangement is clearly shown in Slide 4905. In addition, once Slide 4905 was presented to Dr. Stone, the succeeding questions and answers specifically refer to the arrangement of the fetal oximeter components illustrated in Slide 4905. Thus, references in the bare trial transcript to signals "coming in on the left" or values being displayed "over on the far right" are unintelligible. Absent Slide 4905, Examiner Winakur could have not have made sense of Dr. Stone's Masimo II trial testimony, and accordingly, Slide 4905 is not cumulative to the bare Masimo II trial transcript or any of the other prior art made of record during prosecution of the '986 patent.
- 164. Mr. Kiani, who attended the Masimo II trial and Mr. Jensen, who was litigation counsel for Masimo at the Masimo II trial and upon information and belief, supervised prosecution of the '986 patent, deliberately and intentionally withheld Slide 4905 from the Patent

Examiner. They did so precisely with the purpose of ensuring that the Patent Examiner could not locate Dr. Stone's testimony, or if he did, the Patent Examiner would not be able to understand that testimony. Masimo's and its patent counsel's deception was successful, as Examiner Winakur did not locate, understand or cite the Nellcor fetal oximeter prior art against claim 1 (or any claim) of the '986 patent, even though that prior art anticipates claim 1.

- Examiner stated in the Reasons for Allowance that "Corenman (4,911,167 cited by Applicant) teaches that an oximeter may include frequency domain analysis, *but does not teach performing two different calculations*" (emphasis added). *See* Notice of Allowability at page 2, in the '986 patent prosecution history. This is precisely the feature illustrated by Slide 4905 to Dr. Stone's Masimo II trial testimony.
- 166. As alleged above, it is immaterial that Masimo submitted more than 4000 pages of the Masimo II trial transcript during prosecution of the '986 patent as part of a collection of many thousands of pages of material. As alleged above, Slide 4905 was not cumulative to the bare trial transcript, and without Slide 4905 the Patent Examiner could neither have located Dr. Stone's testimony nor because much of Dr. Stone's testimony refers to what is depicted in Slide 4905 could the Patent Examiner have understood that testimony. But for Masimo's and its counsel's failure to cite during prosecution of the '986 patent the trial exhibits accompanying Dr. Stone's testimony during Masimo II, and particularly Slide 4905, the '986 patent would not have issued.
- 167. All claims of the '986 patent are unenforceable for inequitable conduct because Mr. Kiani and Masimo's patent counsel buried the relevant testimony from Dr. Stone in tens of thousands of pages of irrelevant materials, and moreover, rendered that testimony unintelligible by withholding Slide 4905 from the Masimo II trial.
- 168. The foregoing allegations regarding commission of inequitable conduct regarding the prosecution of the '986 patent are summarized in the following allegations:

- 169. <u>WHO</u>: As alleged above, but for the decision by Mr. Kiani, Mr. Diab, Mr. Jensen and Mr. Grover to deliberately and intentionally bury Dr. Stone's Masimo II trial testimony in a mountain of less relevant material, and further to deliberately withhold Slide 4905 to ensure that the Patent Examiner could not locate that testimony and understand it, at least claim 1 of the '986 patent would not have issued.
- 170. <u>WHAT</u>: As alleged above, Slide 4905 illustrates and renders intelligible the testimony of Dr. Stone at the Masimo II trial, establishing that Nellcor's prior art fetal oximeter included each and every limitation of claim 1 of the '986 patent. Slide 4905 establishes, in conjunction with Dr. Stone's Masimo II testimony referring to that exhibit, that Nellcor's prior art fetal oximeter "determin[es] at least two values corresponding to oxygen saturation based upon at least two alternative methods of using the physiological signals" and "determin[es] a resulting value for oxygen saturation from the at least two values corresponding to oxygen saturation, wherein one of the at least two alternative methods comprises at least one calculation in the frequency domain" as recited in claim 1 of the '986 patent.
- 171. <u>WHERE</u>: As alleged above, Slide 4905 depicts the Nellcor fetal oximeter, illustrates the relationship of the components of that system, and renders Dr. Stone's Masimo II trial testimony intelligible, in a way not possible without possession of Slide 4905.
- establishes that Nellcor's prior art fetal oximeter depicted in Slide 4905 included alternative processing techniques, one of which included frequency domain calculations. This feature was not present in the other prior art made of record during prosecution of the '986 patent, such as Nellcor's Corenman '167 patent which disclosed only a single calculation technique using frequency domain calculations. More specifically, Nellcor's prior art fetal oximeter used processed incoming red and infrared signals with both the Nellcor N-200 Signal Processing Technique (upper block in Slide 4905) and "Frequency Domain Signal Processing Technique" (lower block in Slide 4905). The fetal oximeter determined at least two values corresponding to oxygen saturation based upon at least two alternative methods of using the physiological signals

(Saturation 1 and Saturation 2 depicted in Slide 4905). And at least one of those oxygen saturation values used at least one calculation in the frequency domain (lower box in Slide 4905). The Nellcor fetal oximeter, developed by Dr. Stone prior to 1989, constitutes prior art under 35 U.S.C. § 102 (g). Slide 4095 is not cumulative to the bare trial transcript submitted by Masimo because Dr. Stone's testimony specifically refers to what is depicted in the slide, and the Patent Examiner could not have understood Dr. Stone's testimony without Slide 4905.

173. **HOW**: As alleged above, but for the deliberate withholding of Slide 4905, the Patent Examiner would have rejected at least claim 1 of the '986 patent as anticipated. Slide 4905 shows all of the limitations of claim 1, arranged as claimed in claim 1 of the '986 patent.

### E. Unenforceability of the '154 Patent

174. The application for the '154 patent was filed on August 20, 2007, and claims priority through a chain of patent applications first filed on October 7, 1994; the '154 patent issued on March 24, 2009. Apart from being unenforceable for prosecution laches as described above, the '154 patent further is unenforceable because Masimo and its counsel committed inequitable conduct during prosecution of the '154 patent by misrepresenting the content of other issued Masimo patents, improperly extending the term of the '154 patent, and by withholding certain exhibits to the Yorkey and Baker Declarations in Masimo I, and the trial testimony and exhibits of Dr. Robert T. Stone from the Masimo II trial, as set forth in detail *infra*.

## **Misconduct During Prosecution and Improper Term Extension**

175. Claim 1 of the '154 patent recites: A method of measuring oxygen saturation, the method comprising: (a) obtaining first and second signals that are representative of light of first and second wavelengths detected by a light sensitive detector over a period of time, the detected light of first and second wavelengths being attenuated by body tissue carrying pulsing blood; (b) transforming the first and second signals into the frequency domain; (c) calculating a plurality of possible oxygen saturation values using a plurality of values of each of the transformed first and second signals that correspond to non-zero frequencies; (d) selecting one of the plurality of possible oxygen saturation values as an oxygen saturation measurement based upon an analysis

to determine which of the plurality of possible oxygen saturation values corresponds to the oxygen saturation of the pulsing blood; and (e) outputting the oxygen saturation measurement to a user. (Reference letters added.)

- application claim 1 recited: A method of calculating oxygen saturation from intensity signals resulting from light of first and second wavelengths attenuated by body tissue carrying pulsing blood, the method comprising: (a) receiving at least a portion of an intensity signal from a light sensitive detector capable of detecting light attenuated by body tissue carrying pulsing blood; (b) transforming the intensity signals; and (c) calculating an oxygen saturation by using the transformed intensity signals (Reference letters added.)
- 177. In an Office action dated June 16, 2008, the Patent Examiner, again Examiner Winakur, rejected all of application claims 1-6 as anticipated by Nellcor's '167 Corenman patent. As set forth in the Office action, "Corenman et al. teach a pulse oximeter apparatus and method for frequency domain analysis of detected optical signals (see columns 11 and 12) that includes performing measurements over time, Fourier transforming the measurements, and determining oxygen saturation from the portions of the transformed signals corresponding to the fundamental frequency of the heartbeat. Relative maxima of the processed signals are obtained for use in the calculations. A ratio of red and infrared signals is used in calculating the oxygen saturation. In addition, heart rate information is determined from the fundamental frequency." The claims also were rejected for obviousness-type double patenting over a number of prior Masimo patents, including the '060 patent asserted in the California litigation.
- 178. After a personal interview attended by Examiner Winakur and patent counsel, Messrs. John Grover and Jarom Kesler, Masimo filed an amendment allegedly distinguishing Masimo's claims from Nellcor's Corenman '167 patent. Application claim 1 above was amended to recite: A method of measuring oxygen saturation, the method comprising: (a') obtaining first and second signals that are representative of light of first and second wavelengths detected by a light sensitive detector *over a period of time*, the detected light of first and second wavelengths

being attenuated by body tissue carrying pulsing blood; (b') transforming the first and second signals into the frequency domain; (c') calculating a plurality of possible oxygen saturation values using a plurality of values of each of the transformed first and second signals that correspond to non-zero frequencies; (d') selecting one of the plurality of possible oxygen saturation values as an oxygen saturation measurement based upon an analysis to determine which of the plurality of possible oxygen saturation values corresponds to the oxygen saturation of the pulsing blood; and (e') outputting the oxygen saturation to a user (Reference letters added.). See Amendment dated September 18, 2008, p. 3. Amended application claim 1 issued as claim 1 of the '154 patent.

- 179. With respect to the obvious-type double-patenting rejection, Masimo argued that "The Office Action also rejects Claims 1-6 for non-statutory obviousness-type double patenting in view of Claims 1, 4, 9, and 12 of U.S. Patent 6,745,060, as well as Claims 1 and 4 in view of Claims 4 and 8 of U.S. Patent 6,826,419. The Applicants understand that these double patenting rejections were based on the scope of the previously pending claims. The Applicants submit that such scope has changed with the entry of the present amendment and the Applicants request that the Examiner reconsider the double patenting rejections." *See* Amendment filed September 18, 2008, at pp. 7-8.
- 180. Masimo and its patent counsel, Mr. Grover, committed inequitable conduct in connection with prosecution of the '154 patent by misrepresenting to the Examiner that the amendments discussed above substantially changed the scope of the claims, thereby obviating the obviousness double patenting rejection. The amendments resulting in issued claim 1 of the '154 patent, however, do not patentably distinguish over at least claim 1 of the '060 patent, as shown in the following chart:

Claim 1 of '154 Patent	Claim 1 of '060 Patent
1. A method of measuring oxygen saturation,	1. A method of calculating oxygen saturation
the method comprising:	from intensity signals resulting from light of

	first and second wavelengths attenuated by
	body tissue carrying pulsing blood,
	comprising:
obtaining first and second signals that are	sampling the intensity signals over a first time
representative of light of first and second	period;
wavelengths detected by a light sensitive	
detector over a period of time, the detected	
light of first and second wavelengths being	
attenuated by body tissue carrying pulsing	
blood;	
transforming the first and second signals into	performing a Fourier transform on the sampled
the frequency domain;	intensity signals; and
calculating a plurality of possible oxygen	calculating oxygen saturation by including at
saturation values using a plurality of values of	least a plurality of magnitudes for each of the
each of the transformed first and second	Fourier transformed intensity signals for non-
signals that correspond to non-zero	zero frequencies in the calculation for the first
frequencies;	time period.
selecting one of the plurality of possible	[This step is implicit in the method of the '060
oxygen saturation values as an oxygen	Patent, and explained in the disclosure of the
saturation measurement based upon an analysis	'060 Patent.]
to determine which of the plurality of possible	
oxygen saturation values corresponds to the	
oxygen saturation of the pulsing blood; and	
outputting the oxygen saturation measurement	
to a user.	

- 181. In the above table, there is no substantial difference between the parsing of the preamble and the first elements of the respective claims. Both elements require generating intensity signals resulting from light of first and second wavelengths attenuated by body tissue carrying pulsing blood. There is also no substantive difference between transforming the intensity signals into the frequency domain and performing a Fourier Transform, except that the former step is broader. There is also no patentable distinction between "calculating a plurality of oxygen saturation values using a plurality of values of each of the transformed first and second signals" as recited in the '154 patent and "calculating oxygen saturation by including at least a plurality of magnitudes for each of the Fourier transformed intensity signals" as recited in the '060 patent.
- 182. Still referring to the table above, the final step recited in claim 1 of the '154 patent also does not patentably distinguish over the invention recited in claim 1 of the '060 patent. This is so because one of ordinary skill would have understood that following the step of calculating oxygen saturation in the last step of claim 1 of the '060 patent, necessarily must include a step of selecting which of the plurality of plurality of magnitudes to use in calculating possible oxygen saturation and then outputting the oxygen saturation. The '060 patent, which expired in 2011, indisputably disclosed that step because the '154 patent, even after withdrawing its earlier priority claims, *see infra*, still claims to be a continuation of the U.S. patent application Serial No. 08/320,154, filed October 7, 1994. The '060 patent is also a continuation of U.S. patent application Serial No. 08/320,154, filed October 7, 1994, and accordingly has an *identical disclosure*.
- 183. Moreover, not only did Mr. Grover's deception avoid the necessity for Masimo to file a Terminal Disclaimer tying title to the '154 patent to at least the '060 patent, but Mr. Grover actually dropped several of the earlier claimed priority dates for the '154 patent, thereby extending the term of the '154 patent from March 7, 2011, to nominally October 7, 2014. *See* Amendment filed September 18, 2008, at p. 2. Because the '060 patent has an earliest claimed priority date of March 7, 1991, it expired on March 7, 2011. As demonstrated above, because at

least claim 1 of the '154 patent is not patentably distinct from claim 1 of the '060 patent and extends the term of Masimo's exclusivity on its alleged invention beyond March 7, 2011, the '154 patent is void *ab initio*.

- patent was not accidental. Rather, Mr. Grover intentionally misrepresented the scope of the amended claims of the '154 patent to avoid filing a Terminal Disclaimer that would have tied expiration of the '154 patent to expiration of the '060 patent. That Mr. Grover intended to intentionally mislead Examiner Winakur is evident from the fact that he not only did not file the required Terminal Disclaimer, but instead dropped three earlier priority claims for the '154 patent to extend the term of the '154 patent by an additional three and one-half years.
- 185. Masimo's and its attorney's inequitable conduct in connection with continuation practice leading to issuance of the '154 patent was not isolated to the '060 patent, as described above. Instead, Mr. Grover also misled Examiner Winakur with respect to substantially identical claims that Masimo was simultaneously pursuing in the Patent Office at the same time that it was pursuing the claims of the '154 patent.

## **Deliberate Withholding Of The Yorkey and Baker Declarations**

- 186. Masimo's inventors, Mr. Kiani and Mr. Diab, and its patent counsel, including Mr. Grover, and upon information and belief, Mr. Jensen, further committed inequitable conduct in connection with prosecution of the '154 patent by withholding from the Patent Examiner the Yorkey and Baker Declarations and exhibits, and Dr. Stone's Masimo II trial testimony and exhibits.
- 187. As alleged above, the Amendment dated September 18, 2008, filed in the application for the '154 patent amended application claim 1 require steps of (b') transforming the first and second signals into the frequency domain; (c') calculating a plurality of possible oxygen saturation values using a plurality of values of each of the transformed first and second signals that correspond to non-zero frequencies; (d') selecting one of the plurality of possible oxygen saturation values as an oxygen saturation measurement based upon an analysis to determine

which of the plurality of possible oxygen saturation values corresponds to the oxygen saturation of the pulsing blood; and (e') outputting the oxygen saturation to a user. *See* Amended application claim 1 issued as claim 1 of the '154 patent.

- 188. As shown infra, steps (b'), (c') and (e') are fully disclosed in the cited Corenman patent, so the purported distinction over the prior art consists of "selecting one of the plurality of possible oxygen saturation values as an oxygen saturation measurement based upon an analysis to determine which of the plurality of possible oxygen saturation values corresponds to the oxygen saturation of the pulsing blood." This claimed "analysis to determine which of the plurality of oxygen saturation values corresponds to oxygen saturation of the pulsing blood" may comprise, for example, applying physiologically-based rules to reject invalid values resulting from step (c'). Accordingly, claim 1 of the '154 patent is subject to the same arguments regarding inequitable conduct and invalidity as apply to claim 1 of the '958 patent.
- 189. Corenman discloses a method of computing a blood parameter, in particular blood oxygen saturation, using red and infrared data transformed from the time domain to the frequency domain using a Fourier Transform. *See, e.g.*, Corenman FIG. 10, which discloses practicing in a pulse oximeter each of the following limitations of claim 1 of the '958 patent:
  - (a) obtaining first and second signals that are representative of light of first and second wavelengths detected by a light sensitive detector over a period of time, the detected light of first and second wavelengths being attenuated by body tissue carrying pulsing blood (*See* Corenman FIG. 10, step 4000 "collect 512 data points on each of the Red and IR data");
  - (b) transforming the first and second signals into the frequency domain (*See* Corenman FIG. 10, step 4070 "Compute F.T. [Fourier Transform] of Red and IR data");
  - (c) calculating a plurality of possible oxygen saturation values using a plurality of values of each of the transformed first and second signals that correspond to non-zero frequencies (*See* Corenman FIG. 10, step 4080 "Locate peaks at Heart Rate" and step 4080 "Compute R" [the "ratio of ratios" which is determined by combining the

- transformed Red and Infrared signals to compute a composite signal of the two transformed signals"]);
- (d) selecting one of the plurality of possible oxygen saturation values as an oxygen saturation measurement based upon an analysis to determine which of the plurality of possible oxygen saturation values corresponds to the oxygen saturation of the pulsing blood (*see infra*); and
- (e) and outputting the oxygen saturation measurement to a user. (*See* Corenman FIG. 10, final step "Compute SAT (Usual Nellcor Form)" [in which R value of the "ratio of ratios" is used to look up or compute a value of blood oxygen saturation]).
- 190. The only limitation of claim 1 that is missing from Corenman is the limitation (d) of claim 1 of the '154 patent? performing "an analysis" to determine which of the plurality of possible oxygen saturation values corresponds to the oxygen saturation of the pulsing blood. That feature, however, is fully disclosed in the Nellcor internal documents appended to the Yorkey and Baker Declarations that Mr. Kiani, Mr. Diab and Masimo's counsel deliberately withheld from the Patent Office during prosecution of the '154 patent.
- 191. The Yorkey and Baker Declarations, which were executed in August 2000, had attached thereto Nellcor internal reports created between 1992 and 1994. The Nellcor internal reports predate the 1994 filing date of the '154 patent by several years, and constitute prior art to the '154 patent under at least 35 U.S.C. 102(g). The Yorkey and Baker Declarations and exhibits, and particularly the Nellcor internal reports, are highly material to the patentability of the '154 patent, because they were both well known to Mr. Kiani and Mr. Diab, and attorneys at Knobbe Martens, including Mr. Jensen and Mr. Grover, and because they disclose the key limitation of the '154 patent that was added to secure allowance of that patent. Masimo published the Yorkey and Baker Declarations and exhibits in connection with issuance of Masimo's U.S. Patent No. 7,469,157, which names Mr. Kiani, Mr. Diab and Mr. Weber as co-inventors.
  - 192. More specifically, the Yorkey and Baker Declarations and exhibits thereto

disclose details of Nellcor's O4 pulse oximeter project, begun in 1992, to develop software algorithms that provided valid measurements in the presence of motion noise. As described, e.g., Exhibit 2 to the Yorkey Declaration, that system was designed to process values for the red and infrared signals received from the oximeter sensor to reduce the impact of motion or other noise on the overall average computed value of blood oxygen saturation. *See* O4 Summary dated August 5, 1994, Exhibit 2 to the Yorkey Declaration at page at 1 ("In the fall of 1992, the O4 project began researching oximetry algorithms with the goals of substantially reducing false alarms compared to the N200, and calculating saturation and rate *through periods of motion*.")(emphasis added).

- document dated August 5, 1994 and entitled "O4 Summary": "O4 calculates two saturations, one with the data that has been comb filtered with the current estimate of the heart rate, the other is the raw preprocessed data. *O4 calculates saturation with an adaptive (Kalman) filter that continuously weighs all data by an estimate of the current noise and limits the rate of change to a defined limit (currently 1.3 saturation points per second). Data points which are obviously non-physiological, such as when IR and red values are moving in opposite directions, are deemed invalid and not used to adapt saturation" (emphasis added). The foregoing passage of Exhibit 2 to the Yorkey Declaration plainly discloses the "analysis" step (d) of claim 1 of the '154 patent by analyzing a composite signal using one or more physiologically-based rules. But for Masimo's and its counsel's failure to cite the Yorkey and Baker Declarations and exhibits to the USPTO, the '154 patent would not have issued.*
- 194. As established above, Exhibit 2 to the Yorkey Declaration, in combination with the Corenman patent cited by the Patent Examiner, meets *all* of the limitations of claim 1 of the '154 patent, thus rendering claim 1 *prima facie* invalid. The '154 patent would not have issued had the inventors, Messrs. Kiani and Diab, and Messrs. Jensen and Grover, the patent counsel, cited the Yorkey and Baker materials to the Patent Examiner for review. Had the Examiner known about this prior art Nellcor work as described in Exhibit 2 to the Yorkey Declaration, at

least claim 1 of the '154 patent would not have issued.

- 195. The Yorkey and Baker declarations and exhibits were not cited to the Patent Examiner during prosecution of the '154 patent. Given that Exhibit 2 to the Yorkey Declaration precedes the 1994 filing date for the application for the '154 patent by several months, Masimo would have had to try to "swear behind" the Nellcor documents had they been submitted by Masimo and cited by the Patent Examiner as prior art under 35 U.S.C. § 102(g).
- 196. The Yorkey and Baker Declarations and exhibits are non-cumulative to the other prior art made of record during prosecution of the '154 patent because the Examiner did not identify or cite any other prior art reference as disclosing "an analysis to determine which of the plurality of possible oxygen saturation values corresponds to the oxygen saturation of the pulsing blood."
- Declarations and exhibits since at least August 2000; Mr. Jensen was lead counsel for Masimo in the Masimo I case. And by 2005, Masimo and its counsel had published the Yorkey and Baker Declarations and exhibits in connection with prosecution of Masimo's U.S. Patent No. 7,469,157. By 2007 when the application for the '154 patent was filed, Masimo's inventors and its patent counsel were familiar with Yorkey and Baker Declarations and exhibits, and deliberately chose to withhold those highly material references from the Patent Examiner to prevent having that prior art cited against the '154 patent.
- patent exposed, Masimo and its litigation counsel in the California litigation (which also participated in procuring the '154 patent), now contend that the Yorkey and Baker Declarations were brought to the Patent Examiner's attention in connection with prosecution of the '986 patent. Specifically, Masimo and its counsel now contend that in September 2008, more a year after the patent application for the '154 patent had been filed, and a month after Masimo's counsel met with the Patent Examiner to discuss proposed amendments to put the case in condition for allowance, Masimo's counsel submitted a transmittal letter to the Patent Examiner

informing the Examiner that Masimo had submitted prior art in the files for 24 other Masimo issued patents and pending patent applications. *See* Transmittal Letter dated September 18, 2008. That transmittal letter did not identify the Yorkey and Baker Declarations, or even disclose in which of the other 24 files for the pending applications or issued patents relevant prior art could be found. Masimo also did not provide the Information Disclosure Statements ("IDS's") filed in those 24 other patents and applications.

- 199. Even if Masimo had submitted the IDS's filed in those other cases (prior to issuance of the '154 patent in 2009), which Masimo did not, those IDS's collectively identify many thousands of references, corresponding to more than 100,000 pages of material.
- 200. In connection with its September 18, 2008 IDS, Masimo and its counsel submitted about 350 prior art references, which are actually listed on the IDS's filed for the '154 patent. Examiner Winakur indicated in the file history that he reviewed almost all of references in a single day on October 24, 2008. *See* List of References Cited by Applicant and Considered by Examiner, dated November 13, 2008. Again, assuming a nominal patent length of only 20 pages per reference, Examiner Winakur purportedly read about 7000 pages of prior art on October 24, 2008. To have reviewed 7000 pages of prior art in an 8-hour work day, assuming no interruption, Examiner Winakur would have spent less than 3 seconds, on average, on each page of prior art. There is no indication in the file history for the '154 patent that he ever considered any of the prior art cited in the 24 other patents and applications mentioned in Masimo's transmittal letter, nor given the foregoing schedule, did he have time to do so.
- 201. In view of the circumstances, the single most reasonable inference regarding the '154 patent is that Masimo's inventors and Messrs. Jensen and Grover mentioned the 24 other patent and application files, fully expecting that Examiner Winakur could not review that mountain of prior art, and indeed purposely intended to discourage and prevent Examiner Winakur from reviewing any of the prior art contained in those other patent and application files.
  - 202. Masimo's inventors and its counsel had a duty to cross-cite all material

information irrespective whether the same examiner previously receiving the information is responsible for the patent application at issue, but they deliberately chose not to do so to secure allowance of the '154 patent. Examiner Winakur has examined and issued at least 173 patents to Masimo; he could not possibly be expected to recall that any particular reference amongst the thousands of references Masimo cited in those other applications might apply to the '154 patent years later.

Baker Declarations, and in particular Exhibit 2 to the Yorkey Declaration, was highly material to patentability of at least claim 1 of the '154 patent. Exhibit 2 to the Yorkey Declaration described exactly the type of analysis that Masimo's inventors and its counsel argued was absent from the Corenman reference; but for withholding that material, claim 1 of the '154 patent would not have issued. The content of the Yorkey and Baker Declarations was well known to Masimo's inventors and patent/litigation counsel, and they had in fact cited these materials in many other Masimo applications. Had Masimo or its counsel cited the Yorkey and Baker Declarations and exhibits to the Patent Examiner examining the application for the '154 patent, however, they knew that they could not swear behind the dates of the Nellcor internal reports, in the event the Patent Examiner cited the Nellcor work as prior art. Under the circumstances, the single most reasonable inference regarding Masimo's and its counsel's failure to cite the Yorkey and Baker Declarations and exhibits is that Masimo and its counsel deliberately withheld that information from consideration by the Patent Examiner during prosecution of the '154 patent.

#### **Deliberate Withholding Of The Masimo II Trial Materials**

204. Additionally, Masimo and its counsel committed inequitable conduct in connection with prosecution of the '154 patent, not only for failing to cite the Yorkey and Baker Declarations and exhibits, but also by failing to submit to the USPTO the trial testimony of Dr. Robert T. Stone presented during the Masimo II trial. Mr. Kiani attended the Masimo II trial, and upon information and belief, Mr. Jensen was both litigation counsel in Masimo II and directly participated and/or supervised prosecution of the '154 patent.

- 205. Dr. Stone's trial testimony and exhibits disclose a prototype fetal oximeter and methods developed by Nellcor in the late 1980s, which system also constitutes highly material prior art to the claims of the '154 patent, including claim 1, under 35 U.S.C. § 102(g). But for Masimo's and its counsel's deliberate withholding of the fetal oximeter described in Dr. Stone's trial testimony and exhibits, at least claim 1 of the '154 patent would not have issued.
- 206. As discussed *supra*, during prosecution of the '154 patent, Examiner Winakur identified Corenman, Nellcor's U.S. Patent No. 4,911,167 ("Corenman"), as prior art. *See* Non-Final Rejection mailed June 16, 2008, p. 3. Corenman discloses "a method and apparatus for improving *the calculation of oxygen saturation and other blood constituents*....The processing may occur in the time domain or in the *frequency domain*....In the preferred frequency domain embodiment, the input signals are *Fourier transformed* into its spectral components to form *the composite information*." *See* Corenman, Abstract. The method disclosed in Corenman includes a photodetector that generates a current in response to the *red and infrared light* transmitted in sequence and is converted to a voltage signal. *See* Corenman, col. 2, Il. 3-5.
- 207. As alleged above, the Amendment dated September 18, 2008, filed in the application for the '154 patent amended application claim 1 require steps of (b') transforming the first and second signals into the frequency domain; (c') calculating a plurality of possible oxygen saturation values using a plurality of values of each of the transformed first and second signals that correspond to non-zero frequencies; (d') selecting one of the plurality of possible oxygen saturation values as an oxygen saturation measurement based upon an analysis to determine which of the plurality of possible oxygen saturation values corresponds to the oxygen saturation of the pulsing blood; and (e') outputting the oxygen saturation to a user. *See* Amended application claim 1 issued as claim 1 of the '154 patent.
- 208. As shown infra, steps (b'), (c') and (e') are fully disclosed in the cited Corenman patent, so the purported distinction over the prior art consists of "selecting one of the plurality of possible oxygen saturation values as an oxygen saturation measurement based upon an analysis to determine which of the plurality of possible oxygen saturation values corresponds to the

oxygen saturation of the pulsing blood." This claimed "analysis to determine which of the plurality of oxygen saturation values corresponds to oxygen saturation of the pulsing blood" may comprise, for example, applying physiologically-based rules to reject invalid values resulting from step (c').

- 209. Corenman discloses a method of computing a blood parameter, in particular blood oxygen saturation, using red and infrared data transformed from the time domain to the frequency domain using a Fourier Transform. *See, e.g.*, Corenman FIG. 10, which discloses practicing in a pulse oximeter each of the following limitations of claim 1 of the '958 patent:
  - (a) obtaining first and second signals that are representative of light of first and second wavelengths detected by a light sensitive detector over a period of time, the detected light of first and second wavelengths being attenuated by body tissue carrying pulsing blood (*See* Corenman FIG. 10, step 4000 "collect 512 data points on each of the Red and IR data");
  - (b) transforming the first and second signals into the frequency domain (*See* Corenman FIG. 10, step 4070 "Compute F.T. [Fourier Transform] of Red and IR data");
  - (c) calculating a plurality of possible oxygen saturation values using a plurality of values of each of the transformed first and second signals that correspond to non-zero frequencies (*See* Corenman FIG. 10, step 4080 "Locate peaks at Heart Rate" and step 4080 "Compute R" [the "ratio of ratios" which is determined by combining the transformed Red and Infrared signals to compute a composite signal of the two transformed signals"]);
  - (d) selecting one of the plurality of possible oxygen saturation values as an oxygen saturation measurement based upon an analysis to determine which of the plurality of possible oxygen saturation values corresponds to the oxygen saturation of the pulsing blood (*see infra*); and
  - (e) and outputting the oxygen saturation measurement to a user. (See Corenman FIG. 10,

final step "Compute SAT (Usual Nellcor Form)" [in which R value of the "ratio of ratios" is used to look up or compute a value of blood oxygen saturation]).

- 210. The only limitation of claim 1 that is missing from Corenman is the limitation (d) of claim 1 of the '154 patent? performing "an analysis" to determine which of the plurality of possible oxygen saturation values corresponds to the oxygen saturation of the pulsing blood. That feature and more, however, is disclosed in Dr. Stone's trial testimony at Masimo II regarding Nellcor's fetal oximeter system, which Mr. Kiani, Mr. Diab and Masimo's counsel deliberately withheld from the Patent Office during prosecution of the '154 patent.
- 211. Dr. Stone's testimony and the trial exhibits disclose that Nellcor's fetal oximeter computed blood oxygen saturation via two alternative methods: a first method that used conventional time-based algorithms to compute saturation, and a second frequency domain method in which the red and infrared signals were transformed into the frequency domain and then used to form a composite signal, which in turn was used to compute oxygen saturation. The Nellcor fetal oximeter output two values of oxygen saturation, from which a correct result was selected based on physiologically-based rules. *See* Stone Masimo II testimony, pp. 1819-1820 and Slide 4905.
- 212. Slide 4905 from the Masimo II trial, presented in conjunction with Dr. Stone's testimony shows Red and IR arrows directed to boxes labeled N-200 Signal Processing and Frequency-Domain Signal Process Techniques, thus meeting limitations (a) and (b) of claim 1 of the '154 patent. The Frequency Domain Processing meets limitation (c) of claim 1 of the '154 patent. *See id.* at 1820-1821 and Slide 4905. Dr. Stone further testified that the fetal oximeter arbitrates among the values computed by different approaches by selecting the "best result" from those displayed in the fetal oximetry program, and the selection is based on the characteristics of the physiological signal. *See id.* at 1821. This feature of the Nellcor fetal oximeter satisfies limitations (d) and (e) of claim 1 of the '154 patent. Accordingly, but for the failure by Masimo's inventors and its patent counsel to disclose Dr. Stone's trial testimony and exhibits at the Masimo II trial, at least claim 1 of the '154 patent would not have issued.

- 213. In addition to anticipating at least claim 1 of the '154 patent, the Nellcor fetal oximeter disclosed in Dr. Stone's testimony supplied that which was missing from Corenman, and in combination with Corenman renders at least claim 1 of the '154 patent invalid as obvious. Dr. Stone's trial testimony and trial exhibits are non-cumulative to the prior art cited to and considered by Examiner Winakur during prosecution of the '154 patent because they describe each and every limitation of claim 1, including the purportedly inventive limitation.
- 214. Mr. Kiani and Mr. Diab, who upon information and belief attended the Masimo II trial, and Mr. Jensen, who was both litigation counsel at the Masimo II trial and upon information and belief participated in prosecuting the '154 patent, were aware of Dr. Stone's trial testimony and exhibits. Masimo and its counsel did not provide Dr. Stone's Masimo II trial testimony or exhibits to the Patent Examiner during prosecution of the '154 patent.
- 215. Masimo contends that it brought Dr. Stone's testimony at the Masimo II trial to the Patent Examiner's attention during prosecution of the '154 patent by listing the application file, App. No. 11/154,093, that matured as the '986 patent along with 24 other patent and application files mentioned in a transmittal letter accompanying an IDS filed for the '154 patent. *See* Transmittal Letter dated September 18, 2008. However, that application file does not appear amongst the items actually listed on Masimo's IDS, and Masimo has no reason to believe that the Patent Examiner ever looked beyond the prior art actually submitted during prosecution of the '154 patent. There is no indication in the file history of the '154 patent that the Stone trial testimony from Masimo II was ever considered in connection with examination of the '154 patent. Moreover, the exhibits that accompanied Dr. Stone's Masimo II trial testimony were not even submitted during prosecution in the '986 patent, ensuring that Dr. Stone's Masimo II trial testimony was not even considered during prosecution of that patent.
- 216. As for the Yorkey and Baker Declarations and exhibits, the Nellcor fetal oximeter described in Dr. Stone's Masimo II trial testimony predates the filing date of the '154 patent by many years, and constitutes prior art under 35 U.S.C. § 102(g). Accordingly, Masimo could not have overcome a rejection by the Patent Examiner citing the Nellcor fetal oximeter, and Masimo

could not have filed a declaration "swearing behind" that prior art.

- 217. Mr. Kiani, Mr. Diab and Masimo's patent counsel deliberately and intentionally withheld Dr. Stone's Masimo II trial testimony and exhibits regarding Nellcor's fetal oximeter so that it could not be cited by the Patent Examiner as rendering unpatentable the claims that Masimo sought to obtain in the '154 patent. In view of the foregoing, the single most reasonable inference is that Masimo and its patent counsel deliberately withheld Dr. Stone's Masimo II trial testimony and exhibits to induce the Patent Examiner to allow the claims of the '154 patent. Accordingly, all claims of the '154 patent are unenforceable due for inequitable conduct.
- 218. As alleged above, Masimo and its patent counsel committed inequitable conduct during prosecution of the '154 patent by misleading the Patent Examiner regarding the applicability of his obviousness-type double patenting rejection, improperly extending the term of the '154 Patent. Masimo and its patent counsel also committed inequitable conduct by failing to disclose to the USPTO the Yorkey and Baker materials and by failing to submit to the USPTO Dr. Stone's trial testimony presented during the Masimo II trial, each of which information is both highly material to patentability of the claims of the '154 patent and would have precluded issuance of at least claim 1 of the '154 patent.
- 219. The foregoing allegations regarding commission of inequitable conduct regarding the prosecution of the '154 patent are summarized in the following allegations:
- 220. **WHO**: As alleged above, but for Mr. Kiani's, Mr. Diab's, Mr. Jensen's and Mr. Grover's decision to deliberately and intentionally withhold during prosecution of the '154 patent (1) the Yorkey and Baker Declarations and exhibits and (2) Dr. Stone's Masimo II trial testimony and exhibits, the claims of the '154 patent would not have issued. At least Mr. Grover also committed inequitable conduct in the September 18, 2008, Amendment by misleading the Examiner regarding the applicability of the obviousness-type double patenting rejection set forth in the June 16, 2008 Office action and by improperly extending the term of the '154 patent to extend beyond the term of the '060 Patent.
  - 221. **WHAT**: As alleged above, Masimo and its counsel withheld the Yorkey and

Baker Declarations and exhibits, and in particular Exhibit 2 to the Yorkey Declaration, which discloses at page 3 the use of physiologically based rules to analyze a composite signal based on red and infrared signals, which corresponds to the allegedly inventive "analysis" step (d) of the claim 1 of the '154 patent. This was the only element missing from Corenman, which otherwise anticipated claim 1 of the '154 patent. And separately, as alleged above, Masimo and its counsel withheld Dr. Stone's Masimo II trial testimony and exhibits, which disclosed at pages 1819-1821 and in Slide 4905 a fetal oximeter that generated oxygen saturation values using two different algorithms, including a frequency-based analysis, and then arbitrated between those results using physiologically-based rules to determine a valid output. That testimony and exhibit anticipates at least claim 1 of the '154 patent, or alternatively renders claim 1 unpatentable in combination with Corenman. In addition, Masimo and its patent counsel misled the Patent Examiner that the amendments to claim 1 of the '154 patent obviated the obviousness-type double patenting rejection set forth in the June 16, 2008 Office action, when they did not, and further by withdrawing priority claims so that the term of the '154 patent extends more than three and one-half years beyond expiration of the '060 patent.

- 222. **WHERE**: Page 3 of Yorkey Declaration Exhibit 2 describes in detail at least one physiologically based rule applied to the composite of the red and infrared signals, which corresponds to the analysis step (d) of claim 1 of the '154 patent. Pages 1819 to 1821 of the Masimo II trial transcript and Slide 4905 used in conjunction with that testimony describe the details of the Nellcor fetal oximeter, which similarly discloses step (d) of claim 1 of the '154 patent. Nellcor technology having the features later claimed by Masimo in the '154 patent was developed well before the 1994 filing date for the application that matured as the '154 patent. As to Masimo's misconduct with respect to the double patenting rejection and priority claims, *see*, the Office action dated June 16, 2008 at pp. 3-4 and Amendment dated September 18, 2008 at pp. 2, and 7-8.
- 223. <u>WHY</u>: As alleged above, the description of the application of physiologically-based rules at page 3 of the withheld Exhibit 2 to the Yorkey Declaration, dated August 1994,

supplies the sole claim limitation missing from Corenman. More specifically, Corenman disclosed all limitations of claim 1 of the '154 patent except analysis step (d). Exhibit 2 to the Yorkey Declaration provides that missing limitation, rendering claim 1 of the '154 patent unpatentable. Likewise, Dr. Stone's Masimo II trial testimony and exhibits describe a fetal oximeter developed by Nellcor during Dr. Stone's tenure, prior to 1989, that computed oxygen saturation using alternative calculation methods, one of which was a frequency-based analysis. If the results of these calculations differed, physiologically-based rules were applied to decide whether to select Saturation 1 resulting from the N-200 Signal Processing Branch or Saturation 2 resulting from the Frequency Domain analysis. Nellcor's prior art fetal oximeter therefore provides the sole missing element of at least claim 1 of the '154 patent that was not disclosed in Corenman. As to the Masimo's misconduct with respect to the double patenting rejection and priority claims, no Terminal Disclaimer was ever filed in for the '154 patent, and by improperly withdrawing its earliest priority claims, Masimo has obtained in the '154 patent claims that are insubstantially different than those in the '060 patent (which has the identical disclosure), but do not expire for an additional three and one-half years, improperly extending Masimo's monopoly.

224. HOW: But for the deliberate withholding of the Yorkey and Baker Declarations and exhibits, and separately, withholding of Dr. Stone's Masimo II trial testimony and exhibits, including Slide 4905, Examiner Winakur would have rejected at least claim 1 of the '154 patent, as obvious under 35 U.S.C. § 103 based on Corenman in view of Exhibit 2 to the Yorkey Declaration, under 35 U.S.C. § 102(g) as anticipated by Nellcor's fetal oximeter, or obvious over Nellcor's fetal oximeter in view of Corenman. Nellcor's prior art materials establish that it first invented limitation (d) that Examiner Winakur found to be absent in the other prior art of record. The Yorkey and Baker Declarations and exhibits and Dr. Stone's Masimo II trial testimony was not inadvertently omitted by Masimo and its counsel, but rather deliberately withheld to ensure that Examiner Winakur issued the '154 patent. As to the inequitable conduct relating to misrepresentation to the Patent Examiner, at least Mr. Grover violated his duty of candor in the September 18, 2008, Amendment by misleading the Examiner regarding continued applicability

of the obviousness-type double patenting rejection set forth in the June 16, 2008 Office action, failing to submit a Terminal Disclaimer, and improperly extending the term of the '154 patent.

#### F. Unenforceability of the '222 Patent

- 225. In or about October 1992, at a meeting of the American Society of Anesthesiologists, Mr. Kiani met with several representatives of Nellcor, including Dr. Thomas Yorkey, to give Nellcor a private showing of Masimo's adaptive noise canceller implementation of its pulse oximeter monitor. Subsequently, Nellcor and Masimo entered into an agreement under which Nellcor provided Masimo with raw plethysmographic data for Masimo to run through its adaptive noise canceller algorithm.
- 226. Masimo had further confidential meetings and telephone communications with Nellcor and Dr. Yorkey about Masimo's adaptive noise canceller technology, resulting in further meetings between Nellcor and Masimo in November 1992, and at Nellcor's Hayward office in February, October, and November 1993, all of which Dr. Yorkey attended. Beginning in about November 1992, Masimo and Nellcor began confidentially exchanging "breath-down" test data that had been processed with Masimo's technology; that data was analyzed by Dr. Yorkey and multiple telephone communications took place during this exchange.
- 227. Dr. Yorkey's computation book, for the period March 12, 1993 to November 5, 1994, Masimo II trial exhibit JTX-2721, which was published by Masimo in connection with prosecution of its U.S. Patent No. 7,469,157, shows at page 15 an entry dated March 24, 1993 in which Dr. Yorkey specifically discussed a "Kalman filter for SAT", i.e., calculating blood oxygen saturation. Other Masimo II trial exhibits, such as Joint Exhibit JTX-1004 (which Masimo published in connection with U.S. Patent No. 7,469,157) show that Nellcor invented the use of estimation techniques as early as December 1992.
- 228. In the context of their confidential communications regarding Dr. Yorkey's analysis of the Masimo data, prior to October 1993, Dr. Yorkey informed Mr. Kiani that Nellcor had invented an estimation technique for removing motion artifact noise from a pulse oximeter sensor signal. Upon information and belief, that communication between Dr. Yorkey and Mr.

Kiani occurred in September 1993, although the precise date likely is reflected in Mr. Kiani's invention disclosure for the '812 application, discussed *infra*. An advantage of estimation techniques is that they do not require a noise reference signal as required by the adaptive noise canceller implemented by Masimo.

- based on the input signal and the statistical properties of the signal. By contrast, Masimo's earliest U.S. patent filing, U.S. patent application Serial No. 07/666,060, filed March 7, 1991 ("the '060 application"), only discloses that "the processor (26) of the present invention generates a noise reference signal (n'(t)) which is a combination of only the undesired signal portions and is correlated to both the first and second undesired signal portions. The noise reference signal (n'(t)) is then used to remove the undesired portion of each of the first and second measured signals via an adaptive noise canceler (27)." Masimo's adaptive noise canceller technology, as disclosed in the '060 application, is directed to the generation of a noise reference that is correlated to both the first and second undesired signal portions. In 1993, Kalman filters were viewed by persons of ordinary skill as a distinct class of filters from adaptive noise cancellers.
- 230. The only adaptive noise canceller disclosed in the '060 application is a least squares lattice predictor with a regression filter. Nowhere does the '060 application disclose the use of a Kalman filter, much less even use of a broad class of adaptive noise cancellers for pulse oximetry. In 1992, a Kalman filter would not have been recognized by a person of ordinary skill as an adaptive filter because a Kalman filter does not use a noise reference signal as described in '060 application. Not surprisingly, the '060 application does not contain a single reference to Kalman filters nor does it equate Kalman filters with adaptive noise cancellation. U.S. patent application Serial No. 07/666,060, filed March 7, 1991, does not disclose or suggest that Masimo had invented use of Kalman filtering techniques for pulse oximetry at the time that application was filed.
- 231. After Dr. Yorkey's disclosure to Mr. Kiani of Nellcor's intended use of estimation techniques, Mr. Kiani directed Masimo's patent counsel, Mr. Jensen, to prepare and file a

continuation-in-part (CIP) application of the '060 application with the United States Patent and Trademark Office that disclosed use of various types of adaptive filters that use estimation techniques. Mr. Jensen did so, filing U.S. patent application Serial No. 08/132,812 ("the '812 application") on October 6, 1993. The '222 patent was filed as U.S. patent application Serial No. 08/843,511 ("the '511 application"), on October 6, 1997, as a continuation of the '812 application, and shares a common disclosure with the '812 application. Upon information and belief, Masimo has never revealed the invention disclosure record on which the '812 application was based.

- 232. Like the '060 application, the only adaptive filter disclosed in the '812 application and '222 patent is the adaptive noise canceler embodiment disclosed in the '060 application. However, the '812 application included a single paragraph, which appears at column 49, lines 35-44 of the '222 patent, that states: "Furthermore, it will be understood that correlation cancellation techniques other than joint process estimation may be used together with the reference signals of the present invention. These may include but are not limited to least mean square algorithms, wavelet transforms, spectral estimation techniques, neural networks, Weiner filters, Kalman filters, QR-decomposition based algorithms among others." Spectral estimation techniques, Weiner filters and Kalman filters are all varieties of "estimation techniques."
- 233. Notably, the above passage of the '812 application (and '222 patent) refers to use of the *reference signals of the present invention with* a Kalman filter, and not the use of a Kalman filter, as proposed by Dr. Yorkey by at least March 1993, that does not generate or use reference signals. None of the Kalman filter claims in the '222 patent require a pulse oximeter method in which the reference signals disclosed in the '222 patent are used as inputs to a Kalman filter, even though the generation of a reference signal was part of "the present invention." *See* '222 patent, claims 20, 22-23; col. 49, ll. 36-41. That is because, by the time the '222 patent issued in July 2001, Masimo and its patent counsel had already learned during the course of Masimo I that Nellcor's N395 pulse oximeter used Kalman filters, but without a reference signal. There is no evidence (even today) that Masimo *ever* invented a pulse oximeter algorithm that

used a Kalman filter that does not also require a reference signal generated as disclosed in the '222 patent.

- 234. As explained at pp. 14-18 of the Baker Declaration, Kalman filtering as implemented in the Nellcor N395 oximeter did not generate a reference signal, did not require the first and second undesired signal portions to be correlated, and did not attempt to cancel out the correlated noise from an input signal as disclosed in the '222 patent. However, such correlation is a fundamental requirement of the invention disclosed in the '060 and '812 applications and '222 patent. The '812 application and the '222 patent share a specification, which discloses that the secondary (noise) reference is correlated to the secondary (noise) portion of each of the first (red) and second (infrared) measured signals; the secondary (noise) reference is then used to remove the secondary (noise) portion of each of the first (red) and second (infrared) measured signals via a correlation canceler, such as an adaptive noise canceler. See '222 patent, col. 4, ll. 4-10. This correlation requirement and method of noise cancelation are repeated throughout the specification (see id. at col. 5, Il. 33-38; col. 5, Il. 47-51; col. 9, Il. 17-27; col. 14, Il. 5-8; col. 14, Il. 26-28), but are entirely inconsistent with Kalman filtering as recited in the claims of the '222 patent. One of ordinary skill in the art of adaptive filters in 1993 would not have understood the adaptive noise canceller disclosed in the '060 and '812 applications to include a Kalman filter solution.
- 235. The Kalman filter claims of the '222 patent accordingly lack any written description or enablement, and were inserted by Mr. Kiani and Masimo's patent counsel, Mr. Jensen, based entirely on confidential information learned Dr. Yorkey in 1993 and from the confidential information disclosed by Nellcor during Masimo I.
- 236. For example, claim 16 of the '222 patent recites: A pulse oximeter comprising: (a) an input configured to receive at least two measured intensity signals generated by the detection of at least two wavelengths of light transmitted through body tissue having flowing blood, said intensity signals each having a first portion substantially dependent upon attenuation of said light due to arterial blood, and during motion, a second portion substantially dependent

upon the attenuation of said light due to motion induced noise; and (b) a processor responsive to the at least two intensity signals to determine an approximation of arterial oxygen saturation in the presence of motion induced noise, (c) wherein the processor comprises a Kalman filter. (Reference letters added).

- 237. Claim 16 comes from application pending claim 65 which recited: "The pulse oximeter of Claim 39, *wherein the processor comprises a Kalman filter*." *See* Amendment dated March 20, 2000, p. 5. The Examiner objected to pending claim 65, but noted that the claim would be allowable if rewritten in independent form. *See* Final Rejection dated June 6, 2000, p. 3. That is because pending claim 39, from which pending claim 65 depended, was rejected as anticipated by Frick, U.S. Pat. No. 4,824,242, under 35 U.S.C. § 102(b). *See id*.
- 238. Application claim 39 originally recited: A pulse oximeter comprising: (a) an input configured to receive at least two measured intensity signals generated by the detection of at least two wavelengths of light transmitted through body tissue having flowing blood, said intensity signals each having a first portion substantially dependent upon attenuation of said light due to arterial blood, and during motion, a second portion substantially dependent upon the attenuation of said light due to motion induced noise; and (b) a processor responsive to the at least two intensity signals to determine an approximation of arterial oxygen saturation in the presence of motion induced noise. (Reference letters added.) *See* Amendment dated March 20, 2000, pp. 1-2.
- 239. The Examiner noted that Frick teaches a pulse oximeter system that includes LEDs emitting two wavelengths, a detector, and processing elements for receiving detector signals, calculating a ratio, and determining the oxygen saturation from the ratio; thereby meeting limitation (a). *See* Final Rejection dated June 6, 2000, p. 3. The Examiner further noted that it is inherent that the signals recorded by the detector would include a first portion related to attenuation and a second portion, during motion, related to motion induced noise; thus meeting limitation (b).

- 240. Examiner Winakur allowed claim 16 of the '222 patent after application claim 65 was rewritten in independent form to include all of the limitations of application claim 39. *See* Amendment dated August 18, 2000, pp. 2-3; Notice of Allowance dated August 28, 2000. Patentability of claim 16 therefore is based entirely upon the processor comprising a Kalman filter. As alleged above, Mr. Kiani and his counsel, Mr. Jensen, knew that this had been first invented by Nellcor, and in particular, Dr. Yorkey.
- 241. The single most reasonable inference that can be drawn from the circumstances described above is that the inclusion of the term "Kalman filter," along with other estimation techniques, was the result of communications prior to October 1993 between Dr. Yorkey and Mr. Kiani. Dr. Yorkey's notebook, Masimo II trial Exhibit JTX-2721, shows that at page 15 Dr. Yorkey had conceived of that invention at least by March 1993. There is no evidence that Mr. Kiani, or anyone at Masimo, ever invented the use of a Kalman filter that did not require the reference signal disclosed as "the present invention" in the '222 patent. Mr. Kiani derived the claimed invention of the Kalman filter claims of the '222 patent from Dr. Yorkey, the first and true inventor. Masimo's and its patent counsel's deliberately and intentionally claimed in the '222 patent inventions that Masimo did not invent, rendering the '222 patent invalid and unenforceable.
- 242. Further, the single most reasonable inference for the appearance in the '222 Patent of claims directed to pulse oximeters using Kalman filters that do not require use of the reference signal generated as disclosed in the '222 patent, is that those claims were introduced into the '511 application based on the confidential information disclosed during Masimo I, *i.e.*, that Nellcor's N395 pulse oximeter used various Kalman filters that did not require as an input a reference signal generated as disclosed by Masimo.
- 243. As conclusively established in Masimo I, the '060 application, which shared an identical disclosure with U.S. Patent No. 6,036,642 ("the '642 patent") at issue in Masimo I, does not suggest or disclosed a Kalman filter. This is why in Masimo I the District Court concluded that an "adaptive filter" as disclosed in the '642 patent could not be construed to read on a

Kalman filter. That decision was affirmed on appeal to the Federal Circuit. *See Masimo Corp. v. Mallinckrodt Inc.*, 18 Fed. Appx. 852, 855 (Fed. Cir. 2001). The District Court's dicta in its rulings on the post-verdict motions in Masimo II cannot have "established" that the '060 application disclosed Kalman filters because Masimo I established that it did not.

- 244. <u>WHO</u>: As alleged above, Mr. Kiani, Mr. Diab and Mr. Jensen deliberately and intentionally withheld from the USPTO (1) that Nellcor had first invented the use of estimation techniques to reduce motion noise in pulse oximetry, and that Masimo had derived that invention from Nellcor based upon Mr. Kiani's confidential communications with Nellcor prior to October 1993 and (2) that the claims sought in the '222 patent were based on confidential information learned during discovery from Nellcor in Masimo I, were not invented by Masimo, and have no support in the '222 patent. But for this conduct, the claims of the '222 patent would not have issued.
- 245. WHAT: Masimo derived the invention of using a Kalman filter in a pulse oximeter from Nellcor, whose Dr. Yorkey invented that concept first. The use of Kalman filtering is relevant to many claims of the '222 patent, including at least claim 16; where inclusion of the phrase "wherein the processor comprises a Kalman filter" was the sole basis for allowance. Dr. Yorkey invented the use of estimation techniques, and more specifically, Kalman filters in pulse oximeters no later than March 1993. Dr. Yorkey's communications with Mr. Kiani between November 1992 and prior to October 1993, prompted Mr. Kiani to include a reference to Kalman filters in the '812 application. All other elements of claim 16 are present in the prior art, such as Frick U.S. Pat. No. 4,824,242, discussed in the Examiner's Final Rejection dated June 6, 2000, p. 3. Separately, Mr. Kiani and Mr. Jensen crafted the claims of the '222 patent specifically to exclude requirement in the claims of the '222 patent that the Kalman filter use the reference signal identified as "the present invention" in the '222 patent.
- 246. <u>WHERE</u>: Oral disclosure by Dr. Yorkey to Mr. Kiani during the course of communications and meeting occurring between November 1992 and prior to October 1993, during their collaboration to evaluate Masimo's adaptive noise canceler technology. Based on

his communications with Dr. Yorkey, Mr. Kiani instructed Mr. Jensen to file the '812 application, which refers in a single paragraph (col. 49, ll. 35-44) to using Kalman filters and other estimation techniques with the reference signal generated for use with Masimo's adaptive noise canceler. Dr. Yorkey's prior invention of this technology at least by March 1993, is recorded in Masimo II trial exhibit JTX-2721.

- 247. <u>WHY</u>: As alleged above for claim 16, all of the limitations of claim are disclosed in the prior art, such as in Frick U.S. Pat. No. 4,824,242, discussed in the Examiner's Final Rejection dated June 6, 2000, p. 3. The sole missing limitation in claim 16, was the use of a Kalman filter, invented by Dr. Yorkey, but patented by Mr. Kiani and Mr. Jensen with full knowledge that Masimo had not first invented that technology. Separately and in addition, because the '222 patent only discloses use of a Kalman filter with the noise reference signal as disclosed in the '060 patent, Mr. Kiani and Mr. Jensen knew that there was no support in the '222 patent for claims that did not require the use of that reference signal.
- 248. HOW: But for the deliberate withholding of that the invention of using Kalman filters was derived from Nellcor, which had invented it first, Mr. Kiani and Mr. Jensen could not have obtained claims of the '222 patent, including claim 16, directed to Kalman filters. Had they disclosed Nellcor's prior invention to the Patent Office, the Kalman filter claims of the '222 patent would have been rejected as unpatentable under at least 35 U.S.C. § 102(f) as the claimed invention was invented by another (employees at Nellcor including Dr. Yorkey).

## G. Masimo Knows the '194 and '952 Patents Are Invalid

- 249. Upon information and belief, Masimo and its patent counsel did not confine their attempts to improperly claim inventorship and patent inventions made only by Nellcor. Upon information and belief, Mr. Kiani also met with other potential competitors in the field of pulse oximetry, and attempted to obtain patents covering aspects of pulse oximetry algorithms disclosed by those other competitors to Mr. Kiani.
- 250. Upon information and belief, Mr. Kiani also met with engineers from Philips in 2001 regarding a potential license of his technology to that company. Upon information and

belief, Philips described the algorithms used in its FAST® pulse oximetry technology, and according to Philips, Masimo drafted and filed the claims in U.S. Patent No. 6,699,194 ("the '194 patent"), asserted in the California litigation, in an attempt to cover Philips' FAST® pulse oximetry technology. In doing so, Masimo impermissibly broadened its claims far beyond what it invented and described in its parent application, filed in 1997. *See* Opening Brief In Support Of Defendants' Motion For Summary Judgment Of Invalidity Of U.S. Patent No. 6,699,194 (public version, Dkt. No. 445), filed in *Masimo Corp. v. Philips Elecs. N. Am. Corp. and Philips Medizin Systeme Boblingen GmbH, C.A.* No. 09-80-LPS-MPT (D. Del.) ("the *Philips* litigation").

- 251. In the *Philips* litigation, the defendants moved for summary judgment, *inter alia*, of invalidity of the '222 and '194 patents. On April 2, 2013, Magistrate Judge Mary Pat Thynge in the *Philips* litigation issued a Report and Recommendation that the defendants' motion for summary judgment be granted that claims 17 and 18 of the '222 patent are invalid as failing to provide adequate written description under 35 U.S.C. § 112, first paragraph. *See* Dkt. No. 662, the Philips litigation ("the Report and Recommendation"). The Report and Recommendation further found that all asserted claims of the '194 patent are invalid for lack of written description, more specifically for failing to disclose how to estimate a pulse rate utilizing a signal determined to contain motion artifact. On March 31, 2014, District Court Judge Stark adopted the Magistrate Judge's recommendation as to the '194 patent, ruling the claims asserted against Philips invalid as lacking written description for a method of estimating pulserate where the input signal contained motion artifacts above a threshold.
- 252. The '194 patent issued from a grandchild continuation application of U.S. patent application Serial No. 08/834,194, which issued as U.S. Patent No. 6,002,952 ("the '952 patent"). The '952 patent is asserted in the California litigation, and has an identical disclosure to the '194 patent. Like the claims of the '194 patent, all claims of the '952 patent require apparatus or method steps for estimating a pulserate. Because the Delaware District Court found lack of written description for "estimating a pulserate" as recited in the claims of the '194 patent, then

the claims of the '952 patent must necessarily also be invalid for lack of written description because the same limitation appears in the claims of the '952 patent.

253. At least as of the time of filing of the Report and Recommendation, and since the District Court's adoption of those conclusions, Masimo knows that the claims of the '194 and '952 patents are invalid as lacking written description under 35 U.S.C. § 112, first paragraph, but nonetheless continues to assert these known invalid patents against Shenzhen Mindray.

### CAUSATION, INJURY, DAMAGES AND INJUNCTIVE RELIEF

- 254. As a result of Masimo's anticompetitive conduct and exclusionary practices, the United States market for pulse oximetry products has been unlawfully affected, leading to supracompetitive prices for pulse oximetry products and the exclusion of competitors.
- 255. As a result of Masimo's anticompetitive conduct and exclusionary practices, Mindray USA has suffered threatened and actual antitrust injury by being excluded from offering to sell and selling in the United States market pulse oximetry products that use non-Masimo pulse oximetry technology, and by paying supracompetitive prices for Masimo and Nellcor branded or compatible pulse oximetry sensors and patient cables that it purchases thereby suffering actual losses and overcharges, lost sales and profits.
- 256. As a result, Mindray USA seeks an award of damages in an amount to be proven at trial as well as injunctive relief precluding Masimo from continuing its exclusionary practices.

#### **COUNTERCLAIM 1:**

#### MONOPOLIZATION IN VIOLATION OF THE SHERMAN ACT

- 257. Mindray USA repeats and realleges Paragraphs 1-256 of its Counterclaims above as if fully set forth herein.
- 258. Masimo has monopoly power in the relevant market for pulse oximeter monitors in the United States. Masimo also has monopoly power in the relevant submarkets for standalone pulse oximeter monitors, MPPMs, and OEM circuit boards, and in the markets for pulse oximeter sensors and patient cables. Through its exclusionary conduct in the United States, Masimo has unlawfully acquired and maintained its monopoly power in violation of Section 2 of the Sherman Antitrust Act, 15 U.S.C. § 2.
- 259. Masimo could not maintain its substantial monopoly power in the pulse oximeter market, including the relevant submarkets, but for its tying arrangements, exclusionary agreements, and other anti-competitive conduct. Masimo's monopolization has not been due to growth or development as a consequence of a superior product, business acumen, or historic accident.
- 260. Masimo's monopolization has injured consumers and had a direct, substantial and foreseeable effect on domestic commerce in, and import trade to, the United States market by causing supracompetitive prices for pulse oximetry products and exclusion of competitors.

  Among other things, Masimo's conduct has harmed domestic commerce and import trade by reducing customer choice, restraining output, raising prices and curtailing and/or blocking introduction by Mindray USA of safe, effective, low-cost and durable pulse oximetry products in the United States that use non-Masimo pulse oximetry technology.
- 261. Masimo's acts of monopolization and monopoly maintenance, and the effects of that conduct in the United States, have directly caused antitrust injury and damage, and continues to cause antitrust injury and damage to Mindray USA's business and property by, among other things, hurting sales and imports of Mindray USA, and other non-Masimo pulse oximetry products, in and to the United States and by causing it to pay supracompetitive prices for

Masimo and Nellcor branded or compatible pulse oximetry sensors and patient cables that it purchases. Mindray USA will suffer additional damage in the future if Masimo is permitted to continue its monopolistic conduct. Mindray USA has thereby paid overcharges and lost sales and profits in the United States market. The conduct continues to threaten injury to Mindray USA's business and property, thereby justifying permanent injunctive relief.

262. There is no legitimate business justification for Masimo's exclusionary and anticompetitive conduct that has caused antitrust injury, and continues to cause antitrust injury to Mindray USA, and no purported justification would outweigh the considerable harm to competition in the United States.

# COUNTERCLAIM 2: ATTEMPTED MONOPOLIZATION IN VIOLATION OF THE SHERMAN ACT

- 263. Mindray USA repeats and realleges Paragraphs 1-262 of its Counterclaims above as if fully set forth herein.
- 264. Through its exclusionary conduct, Masimo has unlawfully attempted to acquire a monopoly in violation of Section 2 of the Sherman Antitrust Act, 15 U.S.C. § 2, in the relevant market for pulse oximeter monitors in the United States, including the relevant submarkets for stand-alone pulse oximeter monitors, MPPMs, and OEM circuit boards, and in the markets for pulse oximeter sensors and patient cables.
- 265. Masimo's conduct evidences a specific intent to acquire and maintain monopoly power in the relevant market for pulse oximeters, including the relevant submarkets for standalone pulse oximeter monitors, MPPMs, and OEM circuit boards, and in the markets for pulse oximeter sensors and patient cables.
- 266. Masimo's exclusionary conduct creates a dangerous probability that Masimo will obtain monopoly power in the relevant markets and submarkets, including the power to unilaterally exclude competition, eliminate innovation, and/or raise prices.
- 267. Masimo's attempted monopolization has injured consumers and had a direct, substantial and foreseeable effect on domestic commerce in, and import trade to, the United

States market by causing supracompetitive prices for pulse oximeter products and exclusion of competitors. Among other things, Masimo's conduct has harmed domestic commerce and import trade by reducing customer choice, restraining output, raising prices and curtailing and/or blocking introduction by Mindray USA of safe, effective, low-cost and durable pulse oximetry products in the United States using non-Masimo pulse oximetry technology.

- 268. There is no legitimate business justification for Masimo's exclusionary and anticompetitive conduct that has injured, and continues to injure Mindray USA, and no purported justification would outweigh the considerable harm to competition.
- 269. Masimo's attempted monopolization, and the effects of that conduct in the United States, has directly caused antitrust injured and damage, and continues to cause antitrust injury and damage to Mindray USA's business and property by, among other things, hurting sales and imports of Mindray USA of non-Masimo pulse oximetry products, in and to the United States and by causing it to pay supracompetitive prices for Masimo and Nellcor branded or compatible pulse oximetry sensors and patient cables that it purchases. Mindray USA will suffer additional damage in the future if Masimo is permitted to continue its monopolistic conduct. Mindray USA has thereby paid overcharges and lost sales and profits in the United States market. The conduct continues to threaten injury to Mindray USA's business and property, thereby justifying permanent injunctive relief.

# COUNTERCLAIM 3: ATTEMPTED MONOPOLIZATION IN VIOLATION OF THE SHERMAN ACT

- 270. Mindray USA repeats and realleges Paragraphs 1-269 of its Counterclaims above as if fully set forth herein.
- 271. Through its exclusionary technological ties and contract arrangements, Masimo has unlawfully attempted to acquire a monopoly in violation of Section 2 of the Sherman Antitrust Act, 15 U.S.C. § 2, in the relevant markets for sensors and patient cables.
- 272. Masimo has developed and used the ProCal and X-Cal interfaces with the specific intent of monopolizing the markets for sensors and patient cables. Because of Masimo's

significant market power in the market for pulse oximeter monitors, including the corresponding submarkets for standalone pulse oximeters, MPPMs, and OEM circuit boards, there is a dangerous probability that Masimo will be able to leverage this position to gain monopoly power in the markets for sensors and patient cables.

- 273. Masimo's attempted monopolization has injured consumers and had a direct, substantial and foreseeable effect on domestic commerce in, and import trade to, in the United States by causing supracompetitive prices and exclusion of competitors. Among other things, Masimo's conduct has harmed domestic commerce and import trade by reducing customer choice, restraining output, raising prices and curtailing and/or blocking sales by Mindray USA of safe, effective, low-cost and durable pulse oximetry products that use non-Masimo technology in the United States.
- 274. There is no legitimate business justification for Masimo's exclusionary and anticompetitive conduct that has injured, and continues to injure Mindray USA, and no purported justification would outweigh the considerable harm to competition.
- 275. Masimo's attempted monopolization, and the effects of that conduct in the United States, has directly caused antirust injury and damage, and continues to cause antitrust injury and damage to Mindray USA's business and property by, among other things, hurting sales and imports of Mindray USA of non-Masimo pulse oximetry products, in and to the United States and by causing it pay supracompetitive prices for Masimo and Nellcor branded or compatible pulse oximetry sensors and patient cables that it purchases. Mindray USA will suffer additional damage in the future if Masimo is permitted to continue its monopolistic conduct. Mindray USA has thereby paid overcharges and lost sales and profits in the United States market. The conduct continues to threaten injury to Mindray USA's business and property, thereby justifying permanent injunctive relief.

COUNTERCLAIM 4: CONSPIRACY TO MONOPOLIZE
IN VIOLATION OF THE SHERMAN ACT

- 276. Mindray USA repeats and realleges Paragraphs 1-275 of its Counterclaims as if fully set forth herein.
- 277. Masimo's 2006 Settlement Agreement with Nellcor and subsequent amendments to that Agreement, including the 2011 Second Amendment, constitute an illegal conspiracy to monopolize the market for pulse oximeters in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2.
- 278. Masimo's 2006 Settlement Agreement with Nellcor and subsequent amendments to that Agreement, were entered into with specific intent to create and maintain Masimo's monopoly power in the market for pulse oximeter monitors, including the corresponding submarkets standalone pulse oximeters, MPPMs, and OEM circuit boards. In exchange for cooperation, Masimo granted Nellcor the right to continue selling an infringing pulse oximeter and to collect anti-competitive profits from tied sensor and patient cable sales. Masimo has taken acts in furtherance of its conspiracy with respect to the 2006 Settlement Agreement and subsequent amendments in the past four years and continues to do so. Such acts have and continue to inflict new and accumulating injury to Mindray USA.
- 279. Masimo has taken overt acts in furtherance of this conspiracy within the last four years, including tying sensors and patient cables to pulse oximeter monitors, forcing distributors to accept exclusionary contractual terms, and boycotting manufacturers of third-party sensors and patient cables through the use of the ProCal, X-Cal and DigiCal technologies.
- 280. Masimo's Settlement Agreement with Nellcor and the subsequent amendments to that Agreement, have had a direct, substantial and foreseeable effect on domestic commerce in, and import trade to, in the United States, and continues to do so by causing supracompetitive prices and exclusion of competitors. Among other things, Masimo's conduct has harmed domestic commerce and import trade by reducing customer choice, restraining output, raising prices and curtailing and/or blocking introduction by Mindray USA of safe, effective, low-cost and durable pulse oximetry products in the United States that use non-Masimo pulse oximetry technology.

- 281. There is no legitimate business justification for Masimo's exclusionary and anticompetitive conduct that has injured, and continues to injure Mindray USA, and no purported justification would outweigh the considerable harm to competition.
- 282. Masimo's exclusionary and anti-competitive acts, and the effects of those acts in the United States, have directly caused antitrust injury and damage, and continues to cause antitrust injury and damage to Mindray USA's business and property by, among other things, hurting sales and imports of Mindray USA of non-Masimo pulse oximetry products, in and to the United States and by causing it to pay supracompetitive prices for Masimo and Nellcor branded or compatible pulse oximetry sensors and patient cables that it purchases. Mindray USA will suffer additional damage in the future if Masimo is permitted to continue its anti-competitive conduct. Mindray USA has thereby paid overcharges and lost sales and profits in the United States market. The conduct continues to threaten injury to Mindray USA's business and property, thereby justifying permanent injunctive relief.

# COUNTERCLAIM 5: TYING IN VIOLATION OF THE SHERMAN ACT AND THE CLAYTON ACT

- 283. Mindray USA repeats and realleges Paragraphs 1-282 of its Counterclaims as if fully set forth herein.
- 284. Masimo's anti-competitive tying of pulse oximeters to patient cables and sensors violates Sections 1 and 2 of the Sherman Antitrust Act, 15 U.S.C. §§ 1-2, and Section 3 of the Clayton Act, 15 U.S.C. § 14. This conduct has suppressed competition in the relevant markets for sensors and patient cables.
- 285. Pulse oximeter monitors, patient cables, and sensors used in pulse oximetry are separate relevant markets.
- 286. Masimo controls, either directly or through its control of Nellcor, approximately 80% of the market for pulse oximeter monitors. This dominant position allows Masimo to control prices and exclude competition.

- 287. Masimo has forced customers to purchase Masimo sensors by conditioning the sale of Masimo patented pulse oximeter monitors on the sale of Masimo sensors. It has done so through technological ties, which makes non-Masimo sensors incompatible with Masimo pulse oximeter monitors. It has also enforced the unlawful tie through contractual provisions with distributors.
- 288. Masimo has forced customers to purchase Masimo patient cables by conditioning the sale of Masimo patiented pulse oximeter monitors on the sale of Masimo patient cables. It has enforced the unlawful tie through contractual provisions with distributors and its ProCal and X-Cal interface technologies.
- 289. Masimo's 2006 Settlement Agreement with Nellcor and subsequent amendments to that Agreement, has caused, and continues to cause, Nellcor to force customers to purchase Nellcor sensors and patient cables by conditioning the sale of Nellcor pulse oximeter monitors on the sale of Nellcor sensors. Masimo has threatened to sue Nellcor for infringement of its pulse oximeter patents if it allows competition from third-party sensor manufacturers.
- 290. Through its license agreements with other licensees, Masimo has caused, and continues to cause, such licensees to force customers to purchase Masimo sensors and patient cables by conditioning the sale of Masimo patented pulse oximeter monitors on the sale of Masimo sensors
- 291. Masimo's illegal conduct allows it to extend Masimo's control of the pulse oximeter monitor market into corresponding submarkets for standalone pulse oximeters, MPPMs, and OEM circuit boards. Absent Masimo's illegal conduct, consumers in the United States would purchase sensors and patient cables from third-party suppliers, including Mindray USA. Consumers have been harmed, and continued to be harmed, by Masimo's tying because they have been forced to pay higher prices for sensors and patient cables and have been unable to choose the sensors and patient cables that best suit their needs.
- 292. Masimo's tying scheme has resulted in foreclosure of a substantial amount of commerce in the United States markets for sensors and patient cables, including domestic

commerce and import trade involving sensors and patient cables of competitors, including Mindray USA. By forcing customers to purchase particular sensors and patient cables, Masimo is likely to achieve market power in those markets.

- 293. Masimo's tying scheme has injured consumers and harmed competition in the domestic commerce and import trade by reducing customer choice, restraining output, raising prices and excluding competitors and curtailing and/or blocking introduction by competitors, including Mindray USA of safe, effective, low-cost and durable pulse oximetry products that uses non-Masimo pulse oximetry technology.
- 294. There are no legitimate business justifications for Masimo's requirement that its pulse oximeter monitors be used only with Masimo-branded sensors and patient cables, and no purported justification would outweigh the considerable harm to competition. Similarly, there is no justification for Masimo to cause Nellcor to require that its pulse oximeter monitors be used only with Nellcor-branded sensors, and no purported justification would outweigh the considerable harm to competition.
- 295. Masimo's unlawful tying, and the effects of that conduct in the United States, has directly caused antitrust injury and damage, and continues to cause antitrust injury and damage to Mindray USA's business and property by, among other things, hurting sales and imports of Mindray USA of non-Masimo pulse oximetry products, in and to the United States and by causing it to pay supracompetitive prices for Masimo and Nellcor branded or compatible pulse oximetry sensors and patient cables that it purchases. Mindray USA will suffer additional damage in the future if Masimo is permitted to continue its anti-competitive conduct. Mindray USA has thereby paid overcharges and lost sales and profits in the United States market. The conduct continues to threaten injury to Mindray USA's business and property, thereby justifying permanent injunctive relief.

# COUNTERCLAIM 6: GROUP BOYCOTT IN VIOLATION OF THE SHERMAN ACT

- 296. Mindray USA repeats and realleges Paragraphs 1-295 of its Counterclaims as if fully set forth herein.
- 297. Masimo's exclusion of third parties constitutes a group boycott or concerted refusal to deal, and is illegal *per se* under Section 1 of the Sherman Act. 15 U.S.C. § 1.
- 298. Masimo possesses a dominant position in the relevant market for pulse oximeter monitors, as well as the corresponding submarkets standalone pulse oximeters, MPPMs, and OEM circuit boards.
- 299. Through its agreements with licensees and distributors, Masimo has excluded third-party patient cable and sensor manufacturers from the United States markets for these products by prohibiting licensees and distributors from selling or marketing third-party sensors or patient cables for use with Masimo SET®.
- 300. Masimo has further enforced this exclusive scheme by entering into an agreement with Nellcor, including subsequent amendments within the limitations period, whereby Nellcor must configure its products to exclude third-party sensor and patient cable manufacturers in the United States.
- 301. Because of Masimo's contracts referenced herein, third-party sensor and patient cable manufacturers are excluded from approximately 80% of the market.
- 302. Masimo's contracts referenced herein have injured consumers and had a direct, substantial and foreseeable effect on domestic commerce in, and import trade to, in the United States market by causing supracompetitive prices and exclusion of competitors Among other things, Masimo's conduct has harmed domestic commerce and import trade by reducing customer choice, restraining output, raising prices and curtailing and/or blocking introduction by Mindray USA of safe, effective, low-cost and durable pulse oximetry products in the United States that use non-Masimo pulse oximetry technology.

- 303. There is no legitimate business justification for Masimo's exclusionary and anti-competitive conduct that has caused antitrust injury to, and continues to antitrust injury to, Mindray USA's business and property, and no purported justification would outweigh the considerable harm to competition.
- 304. Masimo's exclusionary and anti-competitive acts, and the effects of those acts in the United States, have directly caused antitrust injury and damage, and continues to cause antitrust injury and damage to Mindray USA's business and property by, among other things, hurting sales and imports of Mindray USA of non-Masimo pulse oximetry products, in and to the United States and by causing it to pay supracompetitive prices for Masimo and Nellcor branded or compatible pulse oximetry sensors and patient cables that it purchases. Mindray USA will suffer additional damage in the future if Masimo is permitted to continue its anti-competitive conduct. Mindray USA has thereby paid overcharges and lost sales and profits in the United States market. The conduct continues to threaten injury to Mindray USA's business and property, thereby justifying permanent injunctive relief.

# COUNTERCLAIM 7: AGREEMENT IN RESTRAINT OF TRADE IN VIOLATION OF THE SHERMAN ACT

- 305. Mindray USA repeats and realleges Paragraphs 1-304 of its Counterclaims as if fully set forth herein.
- 306. As alleged above, Masimo has entered into exclusionary agreements with Nellcor, OEMs, distributors, and hospitals that have unreasonably restrained trade and competition in the relevant United States markets for pulse oximeter monitors, patient cables, and sensors in violation of Section 1 of the Sherman Act, 15 U.S.C. § 1.
- 307. Masimo's exclusionary agreements affect a substantial amount of commerce in the relevant United States markets for pulse oximeter monitors, patient cables, and sensors.
- 308. Masimo's exclusionary agreements have injured consumers and had a direct, substantial and foreseeable effect on domestic commerce in, and import trade to, in the United States by causing supracompetitive prices and excluding competitors. Among other things,

Masimo's conduct has harmed domestic commerce and import trade by reducing customer choice, restraining output, raising prices and curtailing and/or blocking introduction by competitors, including Mindray USA of safe, effective, low-cost and durable pulse oximetry products in the United States that use non-Masimo pulse oximetry technology.

- 309. There is no legitimate business justification for Masimo's exclusionary and anti-competitive conduct that has caused antitrust injury and damage, and continues to cause antitrust injury and damage, to Mindray USA's business and property, and no purported justification would outweigh the considerable harm to competition.
- 310. Masimo's exclusionary and anti-competitive acts, and the effects of those acts in the United States, have directly caused antitrust injury and damage, and continues to cause antitrust injury and damage to Mindray USA's business and property by, among other things, hurting sales and imports of Mindray USA of non-Masimo pulse oximetry products, in and to the United States and by causing it to pay supracompetitive prices for Masimo and Nellcor branded or compatible pulse oximetry sensors and patient cables that it purchases. Mindray USA will suffer additional damage in the future if Masimo is permitted to continue its anti-competitive conduct. Mindray USA has thereby paid overcharges and lost sales and profits in the United States market. The conduct continues to threaten injury to Mindray USA's business and property, thereby justifying permanent injunctive relief.

# COUNTERCLAIM 8: VIOLATION OF SECTION 2 OF THE SHERMAN ACT – WALKER PROCESS MONOPOLIZATION CLAIM

- 311. Mindray USA repeats and realleges Paragraphs 1-310 of its Counterclaims as if fully set forth herein.
- 312. Masimo possesses monopoly power in the relevant United States markets, maintaining a dominant share of a market with high entry barriers.
- 313. As alleged above, the allowance of at least the '222, '986, '958 and '154 patents by the USPTO was procured by Masimo's failure to disclose highly relevant aspects of Nellcor's prior art pulse oximetry algorithms, including prior invention of the use of Kalman filters, the

Yorkey and Baker documents, and fetal oximeter prior art systems material to those patents.

- 314. As alleged above, Masimo failed to disclose highly material prior art during the prosecution of the '222, '986, '958 and '154 patents with the intention of deceiving the USPTO into issuing those patents.
- 315. As alleged above, the USPTO would not have issued the '222, '986, '958 and '154 patents with the claims asserted in the California litigation if Masimo and its patent counsel had not intentionally concealed the existence of the material Nellcor prior art materials.
- 316. As alleged above, at the time Masimo brought the California action, it knew about the Nellcor prior art, and that the Nellcor prior art anticipates and renders the claims of '222, '986, '958 and '154 patents invalid. As of the date of this filing, Masimo further knows that the '194 patent, and consequently, the '952 patent as well, are invalid for lack of written description, as determined by District Court in the *Philips* litigation.
- 317. By asserting the '222, '986, '958, '154, '194 and '952 patents in the California litigation that Masimo knows are invalid and/or unenforceable, Masimo has engaged in willful exclusionary conduct that has caused Masimo's monopoly power in the relevant pulse oximetry United States markets to be maintained, enhanced or acquired, and has significantly diminished the ability of competitors, including Mindray USA to compete fairly in those markets.
- 318. Masimo's actions have caused, and will continue to cause, injury competition in the relevant United States markets and to competitors, including Mindray USA by: (1) creating illegal and artificial barriers to entry into the relevant markets by seeking to enforce invalid and/or fraudulently obtained patents; (2) subjecting competitors, including Mindray USA to the high costs and other substantial burdens of defending themselves against baseless patent infringement actions predicated on invalid and unenforceable patents Masimo knows that competitors, including Mindray USA do not, in any event, infringe; and (3) creating meritless doubt in the minds of the competitors' customers and potential customers, including Mindray USA's customers and potential customers, causing them to forgo purchases of the competitors'

products, including Mindray USA's products that use non-Masimo pulse oximetry technology.

- 319. There is no legitimate business justification for Masimo's exclusionary and anticompetitive conduct that has injured, and continues to injure Mindray USA, and no purported justification would outweigh the considerable harm to competition.
- 320. As a result of Masimo's unlawful conduct in violation of 15 U.S.C. § 2, Mindray USA has suffered and will continue to suffer antitrust injury and damages to its business and property by being excluded from the United States market for pulse oximetry products and by paying supracompetitive prices for Masimo and Nellcor branded or compatible pulse oximetry sensors and patient cables that it purchases. Mindray USA has paid overcharges and lost sales and profits in the United States market. The conduct continues to threaten injury to Mindray USA's business and property, thereby justifying permanent injunctive relief

# COUNTERCLAIM 9: VIOLATION OF SECTION 2 OF THE SHERMAN ACT WALKER PROCESS ATTEMPTED MONOPOLIZATION CLAIM

- 321. Mindray USA repeats and realleges Paragraphs 1-320 of its Counterclaims as if fully set forth herein.
- 322. Masimo's conduct, as alleged above, violates Section 2 of the Sherman Act, 15 U.S.C. § 2.
- 323. By attempting to enforce the '222, '986, '958, '154, '194 and '952 patents in the California litigation that it knows are invalid and unenforceable, Masimo intends to acquire monopoly power in the relevant United States pulse oximetry markets.
- 324. Masimo's attempted monopolization has injured consumers and had a direct, substantial and foreseeable effect on domestic commerce in, and import trade to, in the United States by causing supracompetitive prices and exclusion of competitors. Among other things, Masimo's conduct has harmed domestic commerce and import trade by reducing customer choice, restraining output, raising prices and curtailing and/or blocking introduction by competitors, including Mindray USA of safe, effective, low-cost and durable pulse oximetry products in the United States that use non-Masimo pulse oximetry technology.

- 325. Masimo's actions have caused, and will continue to cause, injury competition in the relevant United States markets and to competitors, including Mindray USA by: (1) creating illegal and artificial barriers to entry into the relevant markets by seeking to enforce invalid and/or fraudulently obtained patents; (2) subjecting competitors, including Mindray USA to the high costs and other substantial burdens of defending themselves against baseless patent infringement actions predicated on invalid and unenforceable patents Masimo knows that competitors, including Mindray USA do not, in any event, infringe; and (3) creating meritless doubt in the minds of the competitors' customers and potential customers, including Mindray's USA customers and potential customers, causing them to forgo purchases of the competitors' products, including Mindray USA's products that use non-Masimo pulse oximetry technology.
- 326. Unless Masimo's baseless patent infringement claims, including its case against Shenzhen Mindray, are dismissed and the asserted patents in the California litigation are declared invalid and unenforceable, Masimo is likely to succeed in acquiring monopoly power because of its dominant position in the relevant markets, the high entry barriers in the market, and the absence of other competitors. Such conduct imposes direct harm to competition in the United States.
- 327. There is no legitimate business justification for Masimo's exclusionary and anticompetitive conduct that has injured, and continues to injure Mindray USA, and no purported justification would outweigh the considerable harm to competition.
- 328. Masimo's attempted monopolization, and the effects of that conduct in the United States, has directly caused antitrust injury and damage, and continues to cause antitrust injury and damage to Mindray USA's business and property by, among other things, hurting sales and imports of Mindray USA of non-Masimo pulse oximetry products, in and to the United States by causing it to pay supracompetitive prices for Masimo and Nellcor branded or compatible pulse oximetry sensors and patient cables that it purchases. Mindray USA will suffer additional damage in the future if Masimo is permitted to continue its monopolistic conduct. Mindray USA has thereby paid overcharges and lost sales and profits in the United States market. The conduct

continues to threaten injury to Mindray USA's business and property, thereby justifying permanent injunctive relief.

### COUNTERCLAIM 10: TORTIOUS INTERFERENCE WITH PROSPECTIVE ECONOMIC ADVANTAGE

- 329. Mindray USA repeats and realleges Paragraphs 1-328 of its Counterclaims as if fully set forth herein.
- 330. Since 2008, Mindray USA has had a commercial relationship with Shenzhen Mindray. Among other things, Mindray USA uses Shenzhen Mindray as its manufacturer of the pulse oximetry products that Mindray USA offers for sale and sells in the United States. Mindray USA purchases its supply of manufactured product in China from Shenzhen Mindray, and then Mindray USA imports that product into the United States. Mindray USA has enjoyed a positive commercial relationship with its China-based supplier, Shenzhen Mindray, with a probability of future economic benefit to Mindray USA.
- 331. At all relevant times, and at least since 2008, Masimo has been aware of the commercial relationship between Mindray USA and Shenzhen Mindray, including, without limitation, that Shenzhen Mindray manufactures pulse oximetry products for Mindray USA.
- 332. At least since 2008, and leading up through July 11, 2012, Masimo has engaged in acts designed to disrupt, and interfere with, the relationship between Mindray USA and Shenzhen Mindray.
- 333. For example, Masimo threatened to disrupt supply of its SET® boards necessary for Shenzhen Mindray's manufacture of pulse oximetry products for Mindray USA, unless Shenzhen Mindray agreed to onerous amendments to the operative contract between Shenzhen Mindray and Masimo. On several occasions between 2008 and July 11, 2012, Masimo carried through on its threat, and either slowed or ceased supply altogether. These acts by Masimo disrupted the relationship between Mindray USA and Shenzhen Mindray.
- 334. In addition, and by way of further example, upon information and belief, Masimo resorted to threatening abuse of contractual rights to pressure Shenzhen Mindray to extend

and/or modify its operative contract with Masimo. When Shenzhen Mindray resisted further amending its agreement in 2011, Masimo formally instituted an audit, and declared its intent to delve into business activities beyond those within the scope of the parties' agreements, including activities with competitors to Masimo that Mindray USA's and Shenzhen Mindray's contracts with Masimo allowed Mindray USA and Shenzhen Mindray to pursue. These acts by Masimo disrupted the relationship between Mindray USA and Shenzhen Mindray.

- 335. But for Masimo's disruption and interference, Mindray USA would purchase, import and sell pulse oximeter monitors that employ Shenzhen Mindray-based pulse oximetry technology, as well as pulse oximeter sensors and patient cables for use with such pulse oximeter monitors.
- 336. But for Masimo's disruption and interference, Mindray USA would have realized additional sales of its products, and would have paid competitive prices for the pulse oximeter sensors and patient cables that it purchased which products would have been sold throughout the United States, including within the State of New Jersey.
- 337. Mindray USA is informed and believes that Masimo's conduct was undertaken with the intent to disrupt and to interfere with Mindray USA's business relationship with Shenzhen Mindray.
- 338. As a result of Masimo's disruption and interference, Mindray USA has been injured in its business and property through the payment of overcharges for Masimo and Nellcor branded or compatible pulse oximetry sensors and patient cables that it purchases, and through loss of present and future profits, by loss of sales of pulse oximeter monitors that employ Shenzhen Mindray-based pulse oximetry technology, as well as pulse oximeter sensors and patient cables compatible with those pulse oximeter monitors, and by paying supracompetitive prices for Masimo and Nellcor branded or compatible pulse oximetry sensors and patient cables that it purchases.
- 339. Mindray USA has suffered and continues to suffer actual damages as a direct result of, and proximately caused by, Masimo's interference.

- 340. Mindray USA is informed and believes that Masimo's acts were willful, malicious, oppressive and undertaken with the intent of harming Mindray USA.
- 341. Unless restrained, Masimo will continue to disrupt Mindray USA's relationship with Shenzhen Mindray, all to Mindray USA's great and irreparable injury, for which damages would not afford an adequate remedy nor completely compensate the injury to Mindray USA's business, reputation and good will.

#### **COUNTERCLAIM 11: COMMON-LAW UNFAIR COMPETITION**

- 342. Mindray USA repeats and realleges Paragraphs 1-341 of its Counterclaims as if fully set forth herein.
- 343. This is a cause of action arises under New Jersey law pertaining to unfair competition, and it relates to Mindray USA's claims arising under the antitrust and patent laws of the United States.
- 344. Masimo's wrongful acts alleged herein, including its exclusionary licensing and distribution practices, illegal tying practices, exclusionary pricing and bundling practices, enforcement of known invalid patents and interference with Mindray USA's business relationship with Shenzhen Mindray, were undertaken with the purpose and intent of injuring Mindray USA's business and property in New Jersey, have harmed competition and restrained trade in the State of New Jersey, have been injurious to consumers, and constitute unlawful, unfair, immoral, unethical, oppressive and fraudulent business practices.
- 345. All of the acts, practices, policies and conduct of Masimo as alleged herein are unfair methods of competition and/or unfair under the common law of New Jersey.
- 346. As a result of Masimo's wrongful acts, Mindray USA has been injured in its business and property through overcharges for Masimo and Nellcor branded or compatible pulse oximetry sensors and patient cables that it purchases and the loss of present and future profits, by loss of sales of pulse oximeter monitors that employ Shenzhen Mindray-based pulse oximetry technology, as well as pulse oximeter sensors and patient cables compatible with those pulse

oximeter monitors and by paying supracompetitive prices for Masimo and Nellcor branded or compatible pulse oximetry sensors and patient cables that it purchases.

- 347. Mindray USA has suffered and continues to suffer actual damages as a result of Masimo's conduct.
- 348. Mindray USA is informed and believes that Masimo's acts were willful, malicious, oppressive and undertaken with the intent of monopolizing the markets for pulse oximeter monitors, sensors and patient cables, and restraining trade and reaping supercompetitive profits in those markets. Masimo's acts have harmed Mindray USA.
- 349. Unless restrained, Masimo will continue to engage in the acts complained of, all to Mindray USA's great and irreparable injury.

# COUNTERCLAIM 12: DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF THE '952 PATENT

- 350. Mindray USA repeats and realleges Paragraphs 1-349 of its Counterclaims as if fully set forth herein.
- 351. By its complaint in the California litigation, Masimo asserts that Mindray USA has infringed the '952 patent.
- 352. Mindray USA has denied Masimo's claim of infringement of the '952 patent, and contends that it does not infringe the '952 patent or any valid or enforceable asserted claim thereof.
- 353. An actual and justiciable controversy has thus arisen between Masimo and Mindray USA concerning the alleged infringement of the '952 patent.
- 354. Pursuant to the Federal Declaratory Judgment Act, 28 U.S.C. § 2201, et seq., Mindray USA is entitled to judgment from this Court finding that the '952 patent is not infringed, directly or indirectly, by Mindray USA.

### COUNTERCLAIM 13: DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF THE '222 PATENT

- 355. Mindray USA repeats and realleges Paragraphs 1-354 of its Counterclaims as if fully set forth herein.
- 356. By its complaint in the California litigation, Masimo asserts that Mindray USA has infringed the '222 patent.
- 357. Mindray USA has denied Masimo's claim of infringement of the '222 patent, and contends that it does not infringe the '222 patent or any valid or enforceable asserted claim thereof.
- 358. An actual and justiciable controversy has thus arisen between Masimo and Mindray USA concerning the alleged infringement of the '222 patent.
- 359. Pursuant to the Federal Declaratory Judgment Act, 28 U.S.C. § 2201, et seq., Mindray USA is entitled to judgment from this Court finding that the '222 patent is not infringed, directly or indirectly, by Mindray USA.

# COUNTERCLAIM 14: DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF THE '086 PATENT

- 360. Mindray USA repeats and realleges Paragraphs 1-359 of its Counterclaims as if fully set forth herein.
- 361. By its complaint in the California litigation, Masimo asserts that Mindray USA has infringed the '086 patent.
- 362. Mindray USA has denied Masimo's claim of infringement of the '086 patent, and contends that it does not infringe the '086 patent or any valid or enforceable asserted claim thereof.
- 363. An actual and justiciable controversy has thus arisen between Masimo and Mindray USA concerning the alleged infringement of the '086 patent.
- 364. Pursuant to the Federal Declaratory Judgment Act, 28 U.S.C. § 2201, et seq., Mindray USA is entitled to judgment from this Court finding that the '086 patent is not infringed, directly or indirectly, by Mindray USA.

# COUNTERCLAIM 15: DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF THE '194 PATENT

- 365. Mindray USA repeats and realleges Paragraphs 1-364 of its Counterclaims as if fully set forth herein.
- 366. By its complaint in the California litigation, Masimo asserts that Mindray USA has infringed the '194 patent.
- 367. Mindray USA has denied Masimo's claim of infringement of the '194 patent, and contends that it does not infringe the '194 patent or any valid or enforceable asserted claim thereof.
- 368. An actual and justiciable controversy has thus arisen between Masimo and Mindray USA concerning the alleged infringement of the '194 patent.

369. Pursuant to the Federal Declaratory Judgment Act, 28 U.S.C. § 2201, et seq., Mindray USA is entitled to judgment from this Court finding that the '194 patent is not infringed, directly or indirectly, by Mindray USA.

# COUNTERCLAIM 16: DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF THE '060 PATENT

- 370. Mindray USA repeats and realleges Paragraphs 1-369 of its Counterclaims as if fully set forth herein.
- 371. By its complaint in the California litigation, Masimo asserts that Mindray USA has infringed the '060 patent.
- 372. Mindray USA has denied Masimo's claim of infringement of the '060 patent, and contends that it does not infringe the '060 patent or any valid or enforceable asserted claim thereof.
- 373. An actual and justiciable controversy has thus arisen between Masimo and Mindray USA concerning the alleged infringement of the '060 patent.
- 374. Pursuant to the Federal Declaratory Judgment Act, 28 U.S.C. § 2201, *et seq.*, Mindray USA is entitled to judgment from this Court finding that the '060 patent is not infringed, directly or indirectly, by Mindray USA.

# COUNTERCLAIM 17: DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF THE '986 PATENT

- 375. Mindray USA repeats and realleges Paragraphs 1-374 of its Counterclaims as if fully set forth herein.
- 376. By its complaint in the California litigation, Masimo asserts that Mindray USA has infringed the '986 patent.
- 377. Mindray USA has denied Masimo's claim of infringement of the '986 patent, and contends that it does not infringe the '986 patent or any valid or enforceable asserted claim thereof.

- 378. An actual and justiciable controversy has thus arisen between Masimo and Mindray USA concerning the alleged infringement of the '986 patent.
- 379. Pursuant to the Federal Declaratory Judgment Act, 28 U.S.C. § 2201, et seq., Mindray USA is entitled to judgment from this Court finding that the '986 patent is not infringed, directly or indirectly, by Mindray USA.

### COUNTERCLAIM 18: DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF THE '958 PATENT

- 380. Mindray USA repeats and realleges Paragraphs 1-379 of its Counterclaims as if fully set forth herein.
- 381. By its complaint in the California litigation, Masimo asserts that Mindray USA has infringed the '958 patent.
- 382. Mindray USA has denied Masimo's claim of infringement of the '958 patent, and contends that it does not infringe the '958 patent or any valid or enforceable asserted claim thereof.
- 383. An actual and justiciable controversy has thus arisen between Masimo and Mindray USA concerning the alleged infringement of the '958 patent.
- 384. Pursuant to the Federal Declaratory Judgment Act, 28 U.S.C. § 2201, et seq., Mindray USA is entitled to judgment from this Court finding that the '958 patent is not infringed, directly or indirectly, by Mindray USA.

# COUNTERCLAIM 19: DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF THE '154 PATENT

- 385. Mindray USA repeats and realleges Paragraphs 1- 384 of its Counterclaims as if fully set forth herein.
- 386. By its complaint in the California litigation, Masimo asserts that Mindray USA has infringed the '154 patent.

- 387. Mindray USA has denied Masimo's claim of infringement of the '154 patent, and contends that it does not infringe the '154 patent or any valid or enforceable asserted claim thereof.
- 388. An actual and justiciable controversy has thus arisen between Masimo and Mindray USA concerning the alleged infringement of the '154 patent.
- 389. Pursuant to the Federal Declaratory Judgment Act, 28 U.S.C. § 2201, et seq., Mindray USA is entitled to judgment from this Court finding that the '154 patent is not infringed, directly or indirectly, by Mindray USA.

# COUNTERCLAIM 20: DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF THE '533 PATENT

- 390. Mindray USA repeats and realleges Paragraphs 1-389 of its Counterclaims as if fully set forth herein.
- 391. By its complaint in the California litigation, Masimo asserts that Mindray USA has infringed the '533 patent.
- 392. Mindray USA has denied Masimo's claim of infringement of the '533 patent, and contends that it does not infringe the '533 patent or any valid or enforceable asserted claim thereof.
- 393. An actual and justiciable controversy has thus arisen between Masimo and Mindray USA concerning the alleged infringement of the '533 patent.
- 394. Pursuant to the Federal Declaratory Judgment Act, 28 U.S.C. § 2201, *et seq.*, Mindray USA is entitled to judgment from this Court finding that the '533 patent is not infringed, directly or indirectly, by Mindray USA.

# COUNTERCLAIM 21: DECLARATORY JUDGMENT OF INVALIDITY OF THE '952 PATENT

395. Mindray USA repeats and realleges Paragraphs 1- 394 of its Counterclaims as if fully set forth herein.

- 396. By its complaint in the California litigation, Masimo asserts that the '952 patent is valid. Mindray USA has denied this allegation and contends that the '952 patent is invalid under 35 U.S.C. §§ 101, 102, 103, 112 and/or 116.
- 397. An actual and justiciable controversy has thus arisen between Masimo and Mindray USA concerning the validity of the '952 patent.
- 398. As alleged above, the '952 patent shares an identical disclosure with the '194 patent, and all claims of the '952 patent include the identical limitation determined by Magistrate Judge Thynge in the Philips litigation to lack written description. Accordingly, all claims of the '952 patent likewise are invalid for lack of written description.
- 399. Pursuant to the Federal Declaratory Judgment Act, 28 U.S.C. § 2201, et seq., Mindray USA is entitled to judgment from this Court finding that the '952 patent is invalid pursuant to 35 U.S.C. §§ 101, 102, 103, 112 and/or 116.

# COUNTERCLAIM 22: DECLARATORY JUDGMENT OF INVALIDITY OF THE '222 PATENT

- 400. Mindray USA repeats and realleges Paragraphs 1- 399 of its Counterclaims as if fully set forth herein.
- 401. By its complaint in the California litigation, Masimo asserts that the '222 patent is valid. Mindray USA has denied this allegation and contends that the '222 patent is invalid under 35 U.S.C. §§ 101, 102, 103, 112 and/or 116.
- 402. As alleged above, all claims of the '222 patent are invalid as lacking written description and having been derived from Nellcor; and in addition, claims 17 and 18 have been determined to be invalid by Magistrate Judge Thyne in the Philips litigation.
- 403. An actual and justiciable controversy has thus arisen between Masimo and Mindray USA concerning the validity of the '222 patent.
- 404. Pursuant to the Federal Declaratory Judgment Act, 28 U.S.C. § 2201, *et seq.*, Mindray USA is entitled to judgment from this Court finding that the '222 patent is invalid pursuant to 35 U.S.C. §§ 101, 102, 103, 112 and/or 116.

# COUNTERCLAIM 23: DECLARATORY JUDGMENT OF INVALIDITY OF THE '086 PATENT

- 405. Mindray USA repeats and realleges Paragraphs 1- 404 of its Counterclaims as if fully set forth herein.
- 406. By its complaint in the California litigation, Masimo asserts that the '086 patent is valid. Mindray USA has denied this allegation and contends that the '086 patent is invalid under 35 U.S.C. §§ 101, 102, 103, 112 and/or 116.
- 407. An actual and justiciable controversy has thus arisen between Masimo and Mindray USA concerning the validity of the '086 patent.
- 408. Pursuant to the Federal Declaratory Judgment Act, 28 U.S.C. § 2201, *et seq.*, Mindray USA is entitled to judgment from this Court finding that the '086 patent is invalid pursuant to 35 U.S.C. §§ 101, 102, 103, 112 and/or 116.

### COUNTERCLAIM 24: DECLARATORY JUDGMENT OF INVALIDITY OF THE '194 PATENT

- 409. Mindray USA repeats and realleges Paragraphs 1- 409 of its Counterclaims as if fully set forth herein.
- 410. By its complaint in the California litigation, Masimo asserts that the '194 patent is valid. Mindray USA has denied this allegation and contends that the '194 patent is invalid under 35 U.S.C. §§ 101, 102, 103, 112 and/or 116.
- 411. An actual and justiciable controversy has thus arisen between Masimo and Mindray USA concerning the validity of the '194 patent.
- 412. As alleged above, all claims of the '194 patent have been determined to be invalid by Magistrate Judge Thynge in the Philips litigation for lacking written description.
- 413. Pursuant to the Federal Declaratory Judgment Act, 28 U.S.C. § 2201, *et seq.*, Mindray USA is entitled to judgment from this Court finding that the '194 patent is invalid pursuant to 35 U.S.C. §§ 101, 102, 103, 112 and/or 116.

#### **COUNTERCLAIM 25: DECLARATORY JUDGMENT**

#### OF INVALIDITY OF THE '060 PATENT

- 414. Mindray USA repeats and realleges Paragraphs 1- 413 of its Counterclaims as if fully set forth herein.
- 415. By its complaint in the California litigation, Masimo asserts that the '060 patent is valid. Mindray USA has denied this allegation and contends that the '060 patent is invalid under 35 U.S.C. §§ 101, 102, 103, 112 and/or 116.
- 416. An actual and justiciable controversy has thus arisen between Masimo and Mindray USA concerning the validity of the '060 patent.
- 417. Pursuant to the Federal Declaratory Judgment Act, 28 U.S.C. § 2201, *et seq.*, Mindray USA is entitled to judgment from this Court finding that the '060 patent is invalid pursuant to 35 U.S.C. §§ 101, 102, 103, 112 and/or 116.

# COUNTERCLAIM 26: DECLARATORY JUDGMENT OF INVALIDITY OF THE '986 PATENT

- 418. Mindray USA repeats and realleges Paragraphs 1- 417 of its Counterclaims as if fully set forth herein.
- 419. By its Complaint, Masimo asserts that the '986 patent is valid. Mindray USA has denied this allegation and contends that the '986 patent is invalid under 35 U.S.C. §§ 101, 102, 103, 112 and/or 116.
- 420. An actual and justiciable controversy has thus arisen between Masimo and Mindray USA concerning the validity of the '986 patent.
- 421. Pursuant to the Federal Declaratory Judgment Act, 28 U.S.C. § 2201, *et seq.*, Mindray USA is entitled to judgment from this Court finding that the '986 patent is invalid pursuant to 35 U.S.C. §§ 101, 102, 103, 112 and/or 116.

# COUNTERCLAIM 27: DECLARATORY JUDGMENT OF INVALIDITY OF THE '958 PATENT

422. Mindray USA repeats and realleges Paragraphs 1- 421 of its Counterclaims as if fully set forth herein.

- 423. By its complaint in the California litigation, Masimo asserts that the '958 patent is valid. Mindray USA has denied this allegation and contends that the '958 patent is invalid under 35 U.S.C. §§ 101, 102, 103, 112 and/or 116.
- 424. An actual and justiciable controversy has thus arisen between Masimo and Mindray USA concerning the validity of the '958 patent.
- 425. Pursuant to the Federal Declaratory Judgment Act, 28 U.S.C. § 2201, et seq., Mindray USA is entitled to judgment from this Court finding that the '958 patent is invalid pursuant to 35 U.S.C. §§ 101, 102, 103, 112 and/or 116.

# COUNTERCLAIM 28: DECLARATORY JUDGMENT OF INVALIDITY OF THE '154 PATENT

- 426. Mindray USA repeats and realleges Paragraphs 1- 425 of its Counterclaims as if fully set forth herein.
- 427. By its complaint in the California litigation, Masimo asserts that the '154 patent is valid. Mindray USA has denied this allegation and contends that the '154 patent is invalid under 35 U.S.C. §§ 101, 102, 103, 112 and/or 116.
- 428. An actual and justiciable controversy has thus arisen between Masimo and Mindray USA concerning the validity of the '154 patent.
- 429. Pursuant to the Federal Declaratory Judgment Act, 28 U.S.C. § 2201, et seq., Mindray USA is entitled to judgment from this Court finding that the '154 patent is invalid pursuant to 35 U.S.C. §§ 101, 102, 103, 112 and/or 116.

# COUNTERCLAIM 29: DECLARATORY JUDGMENT OF INVALIDITY OF THE '533 PATENT

- 430. Mindray USA repeats and realleges Paragraphs 1- 430 of its Counterclaims as if fully set forth herein.
- 431. By its complaint in the California litigation, Masimo asserts that the '533 patent is valid. Mindray USA has denied this allegation and contends that the '533 patent is invalid under 35 U.S.C. §§ 101, 102, 103, 112 and/or 116.
- 432. An actual and justiciable controversy has thus arisen between Masimo and Mindray USA concerning the validity of the '533 patent.
- 433. Pursuant to the Federal Declaratory Judgment Act, 28 U.S.C. § 2201, *et seq.*, Mindray USA is entitled to judgment from this Court finding that the '533 patent is invalid pursuant to 35 U.S.C. §§ 101, 102, 103, 112 and/or 116.

# COUNTERCLAIM 30: DECLARATORY JUDGMENT OF UNENFORCEABILITY BASED ON PATENT MISUSE AND PROSECUTION LACHES

- 434. Mindray USA repeats and realleges Paragraphs 1- 69 of its Answer, each of its Affirmative Defenses, and Paragraphs 1- 433 of its Counterclaims as if fully set forth herein.
  - 435. Masimo has hundreds of issued U.S. patents, but few patents outside the U.S.
- 436. Masimo has engaged in systematic abuse of U.S. patent continuation practice by filing continuation applications resulting in U.S. patents, including several patents asserted herein, more than a decade after the original application in the chain of priority applications, rendering those patents unenforceable under the doctrine of prosecution laches.
- 437. Masimo has impermissibly broadened the physical and/or temporal scope of its patents by means of its abuse of U.S. continuation application practice, and by its anti-competitive and commercially unreasonable demands in connection with licensing such patents.
- 438. Masimo's anti-competitive and commercially unreasonable activities in connection with obtaining and enforcing its '952, '222, '086, '194, '060, '986, '958, '154 and '533

patents, among others, constitutes patent misuse, rendering those patents unenforceable against Mindray USA.

### COUNTERCLAIM 31: DECLARATORY JUDGMENT OF UNENFORCEABILITY OF THE '222 PATENT

- 439. Mindray USA repeats and realleges Paragraphs 1- 438 of its Counterclaims as if fully set forth herein.
- 440. As alleged above, Masimo committed inequitable conduct during prosecution of the '222 patent by attempting to the use of Kalman filters in pulse oximeters, an invention first invented by Nellcor, not Masimo.
- 441. As alleged above, Masimo did not itself invent the use of Kalman filters in pulse oximetry, but learned of that invention from Nellcor through its communications with Dr. Yorkey prior to October 1993, and in further detail in connection with the Masimo I litigation. As alleged above, but for Mr. Kiani's, Mr. Diab's and Mr. Jensen's decision to deliberately and intentionally conceal the true inventorship of the use of Kalman filters from the USPTO, the claims of the '222 patent would not have issued.
- 442. An actual case or controversy exists between Masimo and Mindray USA based on Masimo having filed its complaint in the California litigation against Mindray USA alleging infringement of the '222 patent.
- 443. Mindray USA has been injured and damaged by Masimo filing its complaint in the California litigation asserting the '222 patent.
- 444. Declaratory relief is both appropriate and necessary to establish that the '222 patent is unenforceable and thus cannot be asserted against Mindray USA.

# COUNTERCLAIM 32: DECLARATORY JUDGMENT OF UNENFORCEABILITY OF THE '958 PATENT

445. Mindray USA repeats and realleges Paragraphs 1- 444 of its Counterclaims as if fully set forth herein.

- 446. As alleged above, Masimo committed inequitable conduct during prosecution of the '958 patent by failing to disclose to the USPTO the Yorkey and Baker materials and by failing to submit to the USPTO the trial exhibits needed to understand key portions of the invalidity testimony presented during the Masimo II trial, which information is highly material to patentability of the claims of the '958 patent.
- 447. As alleged above, but for Mr. Kiani's, Mr. Jensen's and Mr. Grover's decision to deliberately and intentionally withhold that information from the USPTO, the claims of the '958 patent would not have issued.
- 448. An actual case or controversy exists between Masimo and Mindray USA based on Masimo having filed its complaint in the California litigation against Mindray USA alleging infringement of the '958 patent.
- 449. Mindray USA has been injured and damaged by Masimo filing its complaint in the California litigation asserting the '958 patent.
- 450. Declaratory relief is both appropriate and necessary to establish that the '958 patent is unenforceable and thus cannot be asserted against Mindray USA.

# COUNTERCLAIM 33: DECLARATORY JUDGMENT OF UNENFORCEABILITY OF THE '986 PATENT

- 451. Mindray USA repeats and realleges Paragraphs 1- 450 of its Counterclaims as if fully set forth herein.
- 452. As alleged above, Masimo committed inequitable conduct during prosecution of the '986 patent by failing to submit to USPTO the trial exhibits needed to understand key portions of the invalidity testimony presented during the Masimo II trial, which information is highly material to patentability of the claims of the '986 patent.
- 453. As alleged above, but for Mr. Kiani's and Masimo's patent counsel's decision to deliberately and intentionally withhold that information from the USPTO, the claims of the '986 patent would not have issued.

- 454. An actual case or controversy exists between Masimo and Mindray USA based on Masimo having filed its complaint in the California litigation against Mindray USA alleging infringement of the '986 patent.
- 455. Mindray USA has been injured and damaged by Masimo filing its complaint in the California litigation asserting the '986 patent.
- 456. Declaratory relief is both appropriate and necessary to establish that the '986 patent is unenforceable and thus cannot be asserted against Mindray USA.

### COUNTERCLAIM 34: DECLARATORY JUDGMENT OF UNENFORCEABILITY OF THE '154 PATENT

- 457. Mindray USA repeats and realleges Paragraphs 1- 456 of its Counterclaims as if fully set forth herein.
- 458. As alleged above, Masimo committed inequitable conduct during prosecution of the '154 patent by failing to disclose to the USPTO the Yorkey and Baker materials and by failing to submit to the USPTO the trial exhibits needed to understand key portions of the invalidity testimony presented during the Masimo II trial, which information is highly material to patentability of the claims of the '154 patent.
- 459. As alleged above, but for Mr. Kiani's and Masimo's patent counsel's decision to deliberately and intentionally withhold that information from the USPTO, the claims of the '154 patent would not have issued.
- 460. An actual case or controversy exists between Masimo and Mindray USA based on Masimo having filed its complaint in the California litigation against Mindray USA alleging infringement of the '154 patent.
- 461. Mindray USA has been injured and damaged by Masimo filing its complaint in the California litigation asserting the '154 patent.
- 462. Declaratory relief is both appropriate and necessary to establish that the '154 patent is unenforceable and thus cannot be asserted against Mindray USA.

#### **COUNTERCLAIM 35:**

#### **INFRINGEMENT OF U.S. PATENT NO. 5,987,343**

- 463. Mindray USA repeats and realleges Paragraphs 1-71 of its Counterclaims above as if fully set forth herein.
- 464. United States Patent No. 5,987,343 ("the '343 Patent"), entitled "Method For Storing Pulse Oximetry Sensor Characteristics," duly and legally issued on November 16, 1999. A true and correct copy of the '343 Patent is attached hereto as Exhibit 1.
- 465. Mindray USA is the owner by assignment of all rights, title and interest in the '343 Patent, including the right to sue and recover for past infringement.
- 466. Upon information and belief, beginning in 2009, Masimo has directly infringed one or more claims of the '343 Patent by making, using, offering for sale, and/or selling pulse oximeter monitors and OEM circuit boards that include its X-Cal technology.
- 467. Upon information and belief, beginning in 2011, Masimo has directly infringed one or more claims of the '343 Patent by making, using, offering for sale, and/or selling disposable sensors that incorporate its X-Cal technology.
- 468. Upon information and belief, beginning in 2009, Masimo actively induced infringement of one or more claims of the '343 Patent by requiring its licensees and distributors to re-engineer their pulse oximeter monitors to accept Masimo OEM circuit boards that include the X-Cal technology.
- 469. Upon information and belief, beginning in 2009, Masimo actively induced infringement of one or more claims of the '343 Patent by requiring its licensees and distributors to use, offer for sale, and/or sell Masimo disposable sensors that include the X-Cal technology.
- 470. Masimo's infringement of the '343 Patent has injured and been to the detriment of Mindray USA and, as a result thereof, Mindray USA is entitled to recover damages adequate to compensate it for the infringement complained of herein, but in no event less than a reasonable royalty.

471. Upon information and belief, Masimo's infringement of the '343 Patent has been and continues to be deliberate and willful. Upon information and belief, Masimo's infringement will continue unless enjoined by this Court.

### **DEMAND FOR JURY TRIAL**

Mindray USA demands a trial by jury of any and all issues in this action so triable.

### PRAYER FOR RELIEF

Wherefore, Mindray USA requests that the Court enter judgment for Mindray USA, and award it the following relief:

- A. Dismiss Masimo's Complaint with prejudice and find that Masimo takes nothing by its claims against Mindray USA;
  - B. Enter judgment in favor of Mindray USA, and against Masimo, on the Complaint;
- C. Declare that Mindray USA has not infringed any of the '952, '222, '086, '194, '060, '986, '958, '154 or '533 patents or any valid asserted claim therein;
- D. Declare that the claims of the '952, '222, '086, '194, '060, '986, '958, '154 and '533 patents are invalid;
- E. Declare that the claims of the '222, '986, '958 and '154 patents are unenforceable for inequitable conduct;
- F. Enter judgment that all of the '533, '060, '986, '958 and '154 patents are unenforceable under the doctrine of prosecution laches.
- G. Declare that all of the '952, '222, '086, '194, '060, '986, '958, '154 and '533 patents are unenforceable against Mindray USA due to patent misuse;
- H. Enjoin Masimo, its assigns, and all those in privity therewith from asserting any of the '952, '222, '086, '194, '060, '986, '958, '154 or '533 patents against Mindray USA or any of its customers or suppliers;
- I. Declare that Masimo has violated the Antitrust laws by virtue of the anticompetitive conduct and exclusionary practices alleged herein;
  - J. Award Mindray USA the damages to which it is entitled under the Antitrust laws,

including treble damages, costs, and attorneys' fees pursuant to 15 U.S.C. § 15(a);

- K. Enjoin Masimo and grant Mindray USA permanent injunctive relief prohibiting Masimo from further engaging in the anti-competitive conduct and exclusionary practices alleged of herein;
- L. Award Mindray USA its actual damages to which it is entitled on Claims 10 and 11, including costs and attorneys' fees;
- M. Award Mindray USA punitive damages against Masimo for its willful, malicious and oppressive acts undertaken with intent to harm Mindray USA, as alleged in Claims 10 and 11;
- N. Enter judgment that Masimo has directly infringed one or more claims of the '343 Patent;

- O. Enter judgment that Masimo has indirectly infringed one or more claims of the '343 Patent;
  - P. Enter judgment that Masimo has willfully infringed the '343 Patents;
- Q. Enter judgment trebling damages for Masimo's willful infringement under 35 U.S.C. § 284;
- R. Issue a preliminary and permanent injunction enjoining Masimo, its officers, agents, servants, representatives, licensees, successors, assigns, and those person in active concert or participation with any of them, from directly or indirectly infringing the '343 Patent;
- S. Award Mindray USA damages adequate to compensate it for the infringement of the '343 Patent but in no event less than a reasonable royalty for use of the invention together with interest and costs under 35 U.S.C. § 284;
- T. Award Mindray USA pre-judgment and post-judgment interest on the damages assessed;
- U. Find this case an exceptional case and award Mindray USA its attorneys' fees and costs under 35 U.S.C. § 285; and
- V. Grant Mindray USA such other and further relief as the Court deems appropriate and just under the circumstances.

Dated: May 21, 2014 FOLEY & LARDNER LLP

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